

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST,  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY,  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND,  
DISTRICT COUNCIL 37, AFSCME -  
HEALTH & SECURITY PLAN; JUNE SWAN;  
MAUREEN COWIE and BERNARD GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri  
corporation, and McKESSON CORPORATION,  
a Delaware corporation,

Defendants.

Civil Action: 1:05-CV-11148-PBS

Judge Patti B. Saris

**REBUTTAL EXPERT DECLARATION OF ROBERT D. WILLIG**

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## **REBUTTAL EXPERT DECLARATION OF ROBERT D. WILLIG**

### **I. INTRODUCTION AND SUMMARY OF CONCLUSIONS**

1. I submitted an expert report in this matter on January 24, 2007 ("January 2007 Willig Report").<sup>1</sup> My qualifications and experience are described in that report.<sup>2</sup> I then submitted a rebuttal expert declaration on May 7, 2007 ("May 2007 Willig Declaration").<sup>3</sup> On October 15, 2007, I submitted an expert declaration ("October 2007 Willig Declaration") in which I responded to certain opinions articulated by plaintiffs' experts, Dr. Raymond S. Hartman and Kimberly P. McDonough.<sup>4</sup>

2. Dr. Hartman submitted his original declaration in support of class certification on July 17, 2006. He updated that declaration on December 20, 2006 ("December 2006 Hartman Declaration"). Dr. Hartman then submitted a rebuttal declaration on March 19, 2007 ("March 2007 Hartman Declaration"). On September 14, 2007, Dr. Hartman submitted a report ("September 2007 Hartman Report") in which he implemented his aggregate damages methodology and expressed his opinion that his model of aggregate damages for the TPP class should apply for all of plaintiffs' proposed class period, August 1, 2001 – March 15, 2005. Also

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1. "Report of Robert D. Willig," January 24, 2007. I understand that this report was submitted as Docket No. 193.
  2. See the January 2007 Willig Report, ¶¶1-4 and Exhibit 1 of that report. Appendix 1 of this declaration contains a list of additional documents and data that I have relied on in producing this declaration.
  3. "Rebuttal Expert Declaration of Robert D. Willig," May 7, 2007. I understand that this declaration was submitted as Docket No. 249.
  4. "Expert Declaration of Robert D. Willig," October 15, 2007. I understand that this declaration was submitted as Docket No. 326.

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on September 14, 2007, Dr. McDonough submitted an expert report ("September 2007 McDonough Report"). On October 29, 2007, Dr. Hartman submitted a new expert report ("October 2007 Hartman Report") and Dr. McDonough submitted a rebuttal report ("October 2007 McDonough Report"). In addition, plaintiffs submitted "tutorials" by Dr. Hartman ("Hartman Video Tutorial") and Dr. McDonough ("McDonough Video Tutorial") on October 29, 2007.

3. I have been asked by counsel for McKesson Corporation ("McKesson") to reply to some of the opinions expressed by Dr. Hartman in the October 2007 Hartman Report and in the Hartman tutorial. In addition, I have been asked to respond to certain opinions contained in the October 2007 McDonough Report and the McDonough tutorial. Nothing in the October 2007 Hartman Report, the Hartman tutorial, the October 2007 McDonough Report or the McDonough tutorial causes me to change the substance of any opinion that I expressed in the January 2007 Willig Report, the May 2007 Willig Declaration or the October 2007 Willig Declaration.<sup>5</sup>

4. The conclusions that I express in this declaration can be summarized as follows:

- Dr. Hartman incorrectly claims that his IMS data capture the amount of reimbursements paid by PBMs to TPPs. He then relies on this incorrect claim further to incorrectly opine: (1) that these IMS data, therefore, indicate the extent to which TPP losses due to the alleged scheme were mitigated by renegotiation and/or contract renewals between TPP and PBMs; and (2) that the extent of that mitigation was essentially zero. Accordingly, in Dr. Hartman's opinion his aggregate damage methodology does not overstate damages, despite the Court's opinion to the contrary. These opinions by Dr. Hartman, like the analysis upon which they rest, are flawed in a number of fundamental ways.
- Dr. Hartman now concedes that his IMS data capture only retail transactions (*i.e.*, PBM payments to retail pharmacies, not TPP reimbursements). However, to

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5. My failure to address any particular claim in either report should not be construed as agreement on my part with that claim.

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overcome this disjunction, Dr. Hartman now asserts a new “constant relationship” assumption which he states, when applied to the IMS retail data, will reveal actual reimbursements at the TPP level. Under this assumption, the PBMs’ profit margins (or spreads) on TPP transactions remain constant over time. Dr. Hartman’s constant relationship assumption, however, is not supported by economic theory or empirical evidence.

- Despite empirical evidence consistent with mitigation and renegotiation, Dr. Hartman’s damages methodology overstates damages by ignoring the implications of mitigation and renegotiation. In particular, the design of Dr. Hartman’s damages methodology overstates harm and understates any mitigation because it ignores the effects of market responses through contractual changes that apply to non-Appendix A drugs (*i.e.*, drugs that did not experience an increased AWP/WAC ratio) and it ignores all market responses other than changes in the discount and dispensing fee contained in PBM contracts with retail pharmacies.
- Dr. Hartman further maintains that his conclusion of essentially zero mitigation is confirmed by the limited competition among PBMs for the business of TPPs. Dr. Hartman’s view of PBM competition continues to be incorrect and inconsistent with the empirical evidence. Moreover, Dr. Hartman’s new theory of limited competition among PBMs implies that TPPs will differ in their market responses to the alleged scheme. Determination of these market responses requires individualized analyses that cannot be accomplished with Dr. Hartman’s damages methodology using the IMS data. Moreover, Dr. Hartman’s theory of limited competition is inconsistent with his theory of a constant or zero profit margin for PBMs on TPP transactions.
- Dr. Hartman offers no new methodology to meet the Court’s requirements for a feasible methodology that will capture mitigation of TPP losses through contract renegotiation or renewal, and thereby prevents overstatement of TPP damages on a class-wide basis. Dr. Hartman admits that he has no data that would enable that determination to be made. Instead, he relies on his IMS data analysis and the constant relationship assumption to argue that there was no mitigation and, therefore, his original damages model is correct. Since those data and the constant relationship assumption do not account for TPP mitigation, his damages methodology continues to overstate damages, whatever is the time period over which it is applied.
- Because members of the percentage co-pay class pay a given percentage of TPP reimbursements, their aggregate damages are derivative of the TPP aggregate damages. Accordingly, all of Dr. Hartman’s errors with respect to TPP aggregate damages apply with equal force to aggregate damages for the percentage co-pay class.

5. My conclusions are based on my experience and expertise as an economist and

my review of documents and data. In producing this declaration, I have relied on documents and

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data listed in my previous report and declarations in this case as well as the additional documents and data listed in Appendix 1 to this declaration. If additional materials are made available to me, I may modify or update my conclusions.

6. The remainder of this declaration is organized as follows: In Section II, I address the errors in Dr. Hartman's claim that his IMS data based on a survey of retail transactions reflect the actual reimbursements paid by TPPs. In Section III, I show that the empirical evidence does not support Dr. Hartman's conclusion that there was no market response to the change in the AWP/WAC ratio. In addition, I show that the biases in Dr. Hartman's damages methodology lead him incorrectly to find damages even if there are none after renegotiation. In Section IV, I address Dr. Hartman's new claims regarding PBM competition. In addition, I point out the inconsistency between his theory that PBMs would not pass on their benefits from the alleged scheme and his new position that there is a constant relationship between the reimbursements paid by TPPs to PBMs and the reimbursements paid by PBMs to retail pharmacies. In Section V, I address the reasons why Dr. Hartman's aggregate damages methodology fails to comply with the Court's instructions. In Section VI, I show that the errors in Dr. Hartman's analysis of TPP aggregate damages apply to aggregate damages for the percentage co-pay consumer class. Section VII summarizes my conclusions.<sup>6</sup>

## **II. DR. HARTMAN FAILS TO SHOW THAT HIS IMS DATA MEASURE TPP REIMBURSEMENTS**

7. In the Class Certification Decision, the Court found that Dr. Hartman's damages methodology overstates damages because the methodology does not account for mitigation

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6. I address Dr. McDonough's claims in Appendix 2 and express additional comments on Dr. Hartman's opinions in Appendix 3.

through renegotiation and contract renewals.<sup>7</sup> This mitigation occurred through complex and diverse changes in various TPP/PBM contract terms. In the September 2007 Hartman Report, Dr. Hartman responded to the Court decision by introducing his statistical analysis of IMS data that purports to show that TPP reimbursements did not experience significant mitigation in response to the increased AWP/WAC ratio. Dr. Hartman described the data from the IMS National Prescription Audit (“NPA”) that he used for his analysis in the following way:

The data I use for my analysis are micro data, that is, data based upon individual real-world transactions or summaries of individual transactions. The transactions reflect claims paid by TPPs and Medicaid and amounts paid by uninsured cash payers.<sup>8</sup>

In essence, Dr. Hartman responded to the Court’s decision by claiming that his methodology accounts for mitigation because it relies on IMS data which themselves reflect mitigating contractual changes.

8. In the October 2007 Willig Declaration, I pointed out that the IMS NPA data are based on a survey of retail pharmacies, not a survey of TPPs or PBMs. Dr. Hartman errs when he claims that transactions in the data reflect actual TPP reimbursements based on the contractual terms negotiated between PBMs and TPPs.<sup>9</sup> Instead, the data are based on a survey of retail

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7. New England Carpenters Health Benefits Fund, et al. v. First DataBank, Inc. and McKesson Corporation, United States District Court, District of Massachusetts, C.A. No. 05-11148-PBS, Memorandum and Order, August 27, 2007 (“Class Certification Order”), at pp. 24-25. October 2007 Hartman Report, at ¶46 and Attachment D, ¶12.

8. September 2007 Hartman Report, at ¶26; Hartman Video Tutorial, at p. 16.

9. Dr. Hartman appears to misunderstand that the IMS NPA data are based on a survey of a sample of retail pharmacies, not a sample of TPPs, when he states, “I note that because the IMS data include retail transactions for a substantial sample of TPPs, it is inconceivable that the IMS data do not include reimbursement claims for GE or CIGNA.” October 2007 Hartman Report, at ¶17; Hartman Video Tutorial, at p. 16. The IMS data used by Dr. Hartman contain observations on the amounts paid to retail from PBMs (including co-payments), Medicaid and cash customers in each month. Although the data are based on transactions that ultimately began with transactions paid by TPPs, there is no measure in that data of the amounts paid by any TPP, including GE and Cigna,



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pharmacies and therefore reflect the contractual terms between PBMs and retail pharmacies. This is hardly a minor technical problem. Dr. Hartman's aggregate damages methodology is put forward as a way to measure the net impact of the alleged scheme on the actual reimbursements paid by TPPs and their members who pay co-insurance as a percentage of the TPP's reimbursement. Within a given transaction, the actual reimbursement paid at the TPP level differs from the amount paid by the PBM to a retail pharmacy because the PBM earns a profit margin on each TPP transaction, often referred to as the PBM's "spread." Accordingly, Dr. Hartman's analysis of IMS data, at best, accounts for PBM squeeze of retail pharmacies through increased discounts and/or reduced dispensing fees in PBM/retail pharmacy contracts. The critical point is that Dr. Hartman's IMS analysis says nothing about mitigation of the impact of the alleged scheme through changes in retail or mail order discounts, dispensing fees and other contractual terms contained in TPP/PBM contracts.<sup>10</sup>

9. In response to this criticism, Dr. Hartman now asserts his "constant relationship" assumption, with which he claims the IMS data in effect can be used to measure the net amount paid by TPPs. That is, according to Dr. Hartman, there is a constant relationship between the amount paid by the PBM to the retail pharmacy and the amount paid by the TPP to the PBM. In other words, despite the fact that the IMS data measure amounts paid at retail by PBMs (including co-pays) and not the actual reimbursements at the TPP level, Dr. Hartman insists that his IMS data actually do measure TPP reimbursements. Dr. Hartman argues that he can

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(...continued)

because PBMs retain a portion of the TPP payments on some or all transactions.

10. For example, evidence in this case shows that District Council 37 ("DC 37") renegotiated its mail order discounts with ESI in the middle of its contract in 2002. This is just one example of mitigation that occurred on the mail order, and not retail, side. Assuming that Dr. Hartman is correct that his IMS data only include retail transactions, he cannot capture any mitigation that occurred only in mail order discount rates.

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therefore use this IMS data with his damages model to account for any mitigation that occurs, and therefore satisfy the Court's instruction to account for mitigation in the damages methodology. Dr. Hartman claims that with his IMS data and constant relationship assumption, he has found no evidence of significant mitigation even after renegotiation of existing contracts.<sup>11</sup> If, as is the case here, it turns out that his data measure something else, then he cannot claim that his aggregate damages methodology satisfies the Court's instruction.

**A. Dr. Hartman's New Assumption of a Constant Relationship Between PBM Payments and TPP Reimbursement is Not Supported by the Evidence and Also Contradicts Dr. Hartman's Own Theory regarding Competition among PBMs**

10. Dr. Hartman attempts to justify his use of the IMS NPA data to measure TPP reimbursements with the new assumption that there is a constant relationship between PBM payments and TPP reimbursements. Dr. Hartman summarizes this new assumption as follows.

As I discuss in my critique of Dr. Willig's October 2007 Declaration in Attachment D to this Declaration, the payments made by PBMs to pharmacies reflect actual costs paid by TPPs because there is a constant relationship between what the PBMs pay the pharmacies and what the TPPs pay the PBMs for brand name drugs. There is *no* evidence that this relationship changed after Mark-Up Scheme was implemented and, in fact, there is ample evidence that it did not change. My use of the IMS data is the functional equivalent of using actual TPP claims data for many TPPs.<sup>12</sup>

11. Dr. Hartman now claims that for many TPPs the amount paid as reported in the IMS data is the TPP's net reimbursement (or  $AA = AWP(1 - d) + df$  using Dr. Hartman's notation).<sup>13</sup> In other words, Dr. Hartman claims that for many TPPs the TPP's net

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11. October 2007 Hartman Report, at ¶14; Hartman Video Tutorial, at p. 16-17.

12. October 2007 Hartman Report, at ¶6 (emphasis in the original); Hartman Video Tutorial, at pp. 16-17. I note that in this new report, Dr. Hartman uses the term "Mark-Up Scheme" to refer to the alleged scheme. In his prior declarations, Dr. Hartman referred to the alleged scheme as the "Scheme" or the "5% Scheme."

13. October 2007 Hartman Report, at ¶7.

reimbursement is identical to the PBM's payment to the retail pharmacy, and therefore the PBM earns zero profit margin on the TPP transactions. Dr. Hartman explains that even if the PBM profit margin is not zero, the margin (or spread) remains constant over time because there is a constant relationship between TPP reimbursements and PBM payments. A constant relationship over time means that the reimbursement at the TPP level changes with the PBM's payment even if they are not equal. That is, a constant relationship is said to imply that whatever profit margin is earned by the PBM from TPP transactions does not change over time.

12. Dr. Hartman's claim that IMS data can be used to determine the TPP's reimbursement itself is impossible unless one assumes all PBMs earn zero profit margin on all TPP transactions.<sup>14</sup> In this way, Dr. Hartman assumes that the observed reimbursement at retail pharmacies is the "functional equivalent" of the TPP reimbursement negotiated between the TPP and the PBM.

13. To illustrate how Dr. Hartman's constant relationship assumption works, I use the following numerical example.<sup>15</sup> In this example, I present two cases: one with zero profit margin for the PBM and one with a positive but constant profit margin for the PBM. Suppose the AWP is \$125, the PBM's discount is 17 percent and the PBM's dispensing fee is \$2.00. Then the reimbursement observed in the IMS data is  $\$105.75 = 0.83 * \$125 + \$2$ . Part of the reimbursement is paid by the consumer to the pharmacy through a co-pay, say \$10. The PBM

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14. As I explain below in Sections II.B and II.C, an additional reason why the assumption that the IMS reported figure is the TPP's reimbursement (AA) is incorrect is that the data include payments from Medicaid and cash customers, and observations where pharmacies reported AWP rather than the actual payment received.

15. Dr. Hartman's assumption that the TPP reimbursement equals the PBM payment is tantamount to an assumption that there is zero margin earned by the PBM on TPP transactions. The zero margin assumption is a more restrictive assumption than a constant relationship between TPP reimbursements and PBM payments at retail

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pays the remaining \$95.75 to the retail pharmacy. If Dr. Hartman assumes that there is zero profit margin on the transaction for the PBM, then he assumes that the discount in the TPP contract is also 17 percent and the dispensing fee in the TPP contract is \$2.00. In that case, the reimbursement at the TPP level would be \$105.75 with the TPP paying the PBM \$95.75 and the consumer paying \$10. The PBM earns zero profit margin in this example because its revenue on the transaction is \$95.75 and its cost is \$95.75. In this example, there is a constant relationship which is that the TPP payment to the PBM always equals the PBM payment to the retail pharmacy.

14. Now assume that the discount at the TPP level is 15 percent while the PBM discount is 17 percent. I still assume for simplicity that the dispensing fee is \$2.00 at both the TPP level and the PBM level. In this example, the reimbursement at the TPP level is  $\$108.25 = 0.85 * \$125 + \$2$ . The co-pay is \$10. So, the TPP pays the PBM \$98.25. The PBM's profit on the transaction now is  $\$2.50 = \$98.25$  received from the TPP -  $\$95.75$  paid to the retail pharmacy. The profit margin as a percentage of AWP is  $2\% = \$2.50/\$125$ . Notice that the profit margin in this example is simply the percentage point difference between the two discounts (17% - 15%). Dr. Hartman's constant profit margin assumption is that there is a constant relationship between the two discounts. This means that an increase in the discount at the PBM level by say one percentage point (to 18% in this example) must be accompanied by a matching increase in the discount at the TPP level by one percentage point (to 16% in this example). Therefore, the constant relationship assumption means here that the PBM's profit margin as a percentage of AWP is constant over time.

15. Dr. Hartman needs the constant relationship assumption to justify his use of the IMS data because he has no data that measure the TPP reimbursement or measure the changes in

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those reimbursements that occurred following the alleged scheme.<sup>16</sup> Instead, he claims that IMS data eliminate the need to know whether the additional costs to the TPPs were mitigated through renegotiation of existing contracts or through new contracts. He further claims that his methodology using the IMS data accurately captures the extent of mitigation that occurred in response to the alleged scheme. And that amount is essentially zero. He asserts, in essence, that a constant relationship between TPP reimbursements and PBM payments at retail means that any mitigation at the TPP level would be observed in the PBM payments at retail which are captured in the IMS data. In this way, Dr. Hartman hopes to satisfy the Court's requirement to account for mitigation in his damages methodology. However, contrary to the assertions, assumptions and hopes of Dr. Hartman, the evidence in this case does not support the assumption that observed PBM payments at retail (as reported by IMS) are the same as, or even in a constant relationship with, the TPP payments to PBMs. In short, Dr. Hartman's constant relationship assumption is unsupported and fails to cure the original flaw in using IMS NPA data based on retail transactions to measure TPP reimbursements paid to PBMs.

**i. There Is No Theoretical or Empirical Basis for the Constant Relationship Assumption**

16. The constant relationship assumption of Dr. Hartman implies that whatever changes in contractual terms that occur in TPP contracts with PBMs are mirrored in the contracts between PBMs and retail pharmacies. In the context of this case, the assumption is that whatever mitigation or "push-back" occurred at the TPP level in response to the increased AWP/WAC ratio was no greater than the mitigation or squeeze that occurred in the PBMs' contracts with

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16. Dr. Hartman concedes that there is no data source that shows what contracts were renegotiated over time. October 2007 Hartman Report, at ¶34. ("There is no data base that would allow me to identify and exclude on a Class-wide basis those contracts that were 'renegotiated in response to the increase.'")

retail pharmacies. Moreover, Dr. Hartman's implicit assumption is that the only parameter which can change in response to the increased AWP/WAC ratio is the discount off AWP. Dr. Hartman's constant relationship assumption is, in essence, that the change in the discount at the TPP level is no greater than the change in the discount at the PBM level.<sup>17</sup>

17. There is no theoretical or empirical support for Dr. Hartman's constant relationship assumption. Verifying that the assumption is valid could not be accomplished on a common class-wide basis, but would rather necessitate individualized inquiry into the arrangements pertaining to each TPP. Indeed, there are a number of plausible scenarios that would generate increases in discounts (or other contractual parameter changes) that are greater in TPP/PBM contracts than the increases in discounts in PBM/retail pharmacy contracts. For example, if a PBM benefits through increased profit margins in its mail order business (a

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17. In Attachment E of the October 2007 Hartman Report, Dr. Hartman attempts to modify his position regarding the "constant relationship" between PBM and TPP reimbursements by claiming that even if there is "push-back" among TPPs, the magnitude of such push-back is less than the magnitude of the PBMs' squeeze of retail pharmacies. For this reason, Dr. Hartman contends that his use of the IMS data results in a "conservative" measure of damages that understates the true harm. The problem for this contention of Dr. Hartman is that his claim that his measure is conservative requires the specific individualized finding that the magnitude of each TPP's push-back is less than or equal to the magnitude of PBMs' squeeze. In particular, Dr. Hartman states, "**Hence, the use of IMS data will always provide a conservative estimate of TPP damages unless the PBMs were to give back more than they were able to negotiate from the retailers.**" Attachment E, at p. 2 (emphasis in original). However, it is critical to recognize that if this arbitrary assumption fails to hold, then Dr. Hartman's use of IMS data is not "conservative" and instead overstates damages. Ascertaining whether or not this key assumption holds requires individualized inquiries into each TPP.

In the October 2007 Hartman Report, Attachment E., at p. 1, Dr. Hartman also makes the observation that if the discount off AWP at the PBM level is greater than the discount off AWP at the TPP level, then his measure of damages using the IMS data at the PBM level will slightly understate damages at the TPP level. This is a simple mathematical finding and requires the unsupported assumption that the only market response to the alleged scheme is a change in the discounts off AWP and that the change in discount at the TPP level is no greater in magnitude than the change in discount at the PBM level.

scenario that Dr. Hartman claims is likely), the PBM may seek to induce greater usage of its higher profit margin mail order business by increasing discounts to TPPs. Under this scenario, the discounts at the TPP level would increase while there would be no change in the discounts at the retail level – the level observed in the IMS data.

18. Another plausible scenario is that in response to increased profit margins at retail following implementation of the alleged scheme, one PBM negotiates an increased discount with retail pharmacies while its rivals do not. That PBM then seeks to increase its market share with TPPs by offering greater discounts off AWP to TPPs. Some or all of the rival PBMs may choose to match the increased discounts. The result would be increased discounts at the TPP level that are greater in magnitude than increased discounts at the PBM level.

19. Other plausible scenarios arise once I relax the Hartman assumption that the only parameter that can adjust in response to the increased AWP/WAC ratio is the discount off AWP. Once the PBM attempts to squeeze excess profit from the retailers using means other than the discount off AWP, while each TPP mitigates or pushes back using parameters other than the discount, there is no longer any calibration for the assumption that the change in the discount at the TPP level can be no greater than the change in the discount at the PBM level.

20. Determining whether Dr. Hartman's critical assumption is correct therefore would require an examination of the market responses at the TPP level in order to compare those responses with market responses at the retail level. Such an examination requires collection of data at the individualized TPP level in addition to data at the retail level. Without doing this individualized analysis, Dr. Hartman had continued to make an unsupported and invalid assumption that whatever the market response is at the TPP level, that response must be less than or equal to the measured response at the retail level.



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**ii. Publications Cited by Dr. Hartman Do Not Support His Use of IMS Data to Measure TPP Reimbursements**

21. Dr. Hartman attempts to justify the way he uses IMS NPA by citing numerous academic articles, government reports and industry reports that employ IMS data. There is no doubt that IMS data are widely used for many purposes, just not Dr. Hartman's purpose. I have reviewed the publications cited in Dr. Hartman's Attachment B and conclude that none of them uses IMS NPA data to measure payments by TPPs.<sup>18</sup> Furthermore, none of the publications indicate that Dr. Hartman's approach to the IMS is a viable method for determining TPP reimbursements and market responses in TPP reimbursements.<sup>19</sup> Table 1 summarizes the uses of IMS data in the publications. The use of the IMS NPA data by academics and industry experts for one particular purpose, say to summarize total prescription drug sales in a year, does not justify the inappropriate use of the same data to measure a variable (in this case TPP reimbursement) that is not contained in the data.

**iii. Dr. McDonough Contradicts Dr. Hartman's Constant Relationship Assumption**

22. Plaintiffs' expert, Dr. McDonough, apparently disagrees with Dr. Hartman that PBM payments equal TPP reimbursements when she contends that PBMs typically earn a

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18. Some articles use the term "third-party payor" to refer to TPPs and PBMs jointly. These articles, however, do not use the IMS data to measure reimbursements at the TPP level as opposed to payments by PBMs to retail pharmacies.

19. IMS itself indicates that its data do not report TPP reimbursements paid to PBMs. See Declaration of Darrell Philpot, October 15, 2007, at ¶5. ("For transactions where the pharmacy receives reimbursement from a PBM, the pharmacy reports what the pharmacy received from the PBM, and IMS records this amount as a payment from a private payor. IMS data does not capture any information on the amounts paid by a third party payor to a PBM, and these payments are not reflected in data provided through the NPA or any other service offered by IMS.")



positive spread on branded drug transactions.<sup>20</sup> Dr. McDonough also notes that the PBM spread typically is not publicized, which indicates Dr. Hartman's inability to make a valid claim that the profit margin is zero or constant without individualized data on the size and dynamics of PBM profit margins or the amounts paid at the TPP level.

**iv. Dr. Hartman's Constant Relationship Assumption Also Contradicts His Own Theory of Limited PBM Competition**

23. Dr. Hartman's theory of a zero or positive constant profit margins for PBMs on their TPP transactions contradicts his theory that competition among PBMs is insufficient to generate a pass-through of the benefits from the alleged scheme. Dr. Hartman justifies his contention that there is virtually zero mitigating market response to the alleged scheme on the basis of his theory that PBMs do not compete sufficiently for TPP business to pass on any of the benefit from the alleged scheme.<sup>21</sup> There are two principal ways in which PBMs may have benefited from the increased AWP/WAC ratio. Like retail pharmacies, vertically integrated PBMs that own mail order pharmacies could have benefited from the increased margin between AWP and WAC. In addition, PBMs might have benefited by changing contractual terms (*e.g.*, increasing the discount off AWP) with retail pharmacies to squeeze some of the excess profit out

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20. See Kimberly P. McDonough, "Pharmacy Benefits Managers," in *Handbook of Pharmaceutical Public Policy*, eds. Thomas R. Fulda and Albert I. Wertheimer, 2007, ("McDonough Article"); October 2007 McDonough Report, at p. 5 and September 2007 McDonough Report, at p. 13. Furthermore, Schondelmeyer and Wrobel, in an article cited in the October 2007 Hartman Declaration, fn 35, report that PBMs earn a positive profit margin. (Stephen W. Schondelmeyer and Marion V. Wrobel, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," Final Report, Abt Associates Inc., Prepared for Centers for Medicare and Medicaid Services, August 30, 2004, p. 13).

21. See March 2007 Hartman Declaration, ¶¶3-4 and Attachment C, ¶3; September 2007 Hartman Report, ¶¶62-65; October 2007 Hartman Report, ¶¶41-47; and Hartman Video Tutorial, at p. 2-3.

of retail pharmacies. Dr. Hartman contends that PBMs had no interest in sharing knowledge of the increased AWP/WAC ratio with TPPs or sharing any of the benefit. According to Dr. Hartman, competition among PBMs would not force them to share any of the benefit.<sup>22</sup> Dr. Hartman's theory implies that PBM profit margins can increase on TPP transactions due to an artificial increase in AWP and that the increased profit margin will not be competed away.

24. The problem for Dr. Hartman's new theory of zero or constant profit margins for PBMs on their TPP transactions is that it is inconsistent with his own expressed view that the lack of competition among PBMs would allow them to increase their profit margins as a result of the alleged scheme.

**v. The Constant Relationship Assumption Does Not Hold Because Adjustments Apply to Non-Appendix A Drugs**

25. As I explain in more detail below in Section III.B, Dr. Hartman's methodology fails to account for mitigation through non-Appendix A drugs. This arises because TPP contractual terms (*e.g.*, discount off AWP) apply to essentially all self-administered brand name prescription drugs, not just Appendix A drugs, which account for only about half of the overall sales volume of self-administered drugs.<sup>23</sup> This leads to a general overstatement of damages under Dr. Hartman's methodology, but also undermines his constant relationship assumption underlying his reliance on the IMS data. The observed mitigation using the IMS data on a sample of Appendix A drugs does not indicate the full mitigation that occurred at the TPP level because much of that mitigation occurs on transactions involving non-Appendix A drugs.

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22. October 2007 Hartman Report, ¶63; Hartman Video Tutorial, at p. 2,6.

23. January Willig Report, at Table 1.

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**vi. The Constant Relationship Assumption is Undermined by Market Responses Not Captured in the IMS Data**

26. As I explain in more detail below in Section III.C, Dr. Hartman's IMS data fail to capture mitigating market responses in a number of parameters that are not observed in the IMS data (*e.g.*, reductions in TPPs fees, increases in rebates pass-through percentages). This is a general problem with his overall methodology, leading to an overstatement of damages and a masking of mitigation that may occur. This problem is further exacerbated by the use of IMS data at the retail level because Dr. Hartman must assume that any market response or squeeze of retailers by PBMs happens only through increases in PBMs' discounts. His constant relationship assumption is that this change in discount is identical to the unobserved change in discount at the TPP level. Once it is recognized that market responses are complex and operate through a mix of contractual and non-contractual parameters, it follows logically that there is no necessary or even likely constant relationship between the PBM discount and the TPP discount.

27. In summary, Dr. Hartman's assumption of constant relationships between the amounts paid by PBMs to retail pharmacies and the reimbursements paid by TPPs is just an unsupported conjecture by Dr. Hartman that contradicts his theory of limited competition among PBMs. Dr. Hartman needs the constant relationship assumption because his IMS data measure retail transactions rather than TPP payments, the information that he needs for his damages methodology to not overstate damages. This mis-measurement is one reason why his damages methodology is not feasible for providing an accurate and unbiased estimate of aggregate damages.

**B. Dr. Hartman's IMS Data Further Mis-Measure TPP Transactions by Including Payments from Medicaid and Cash Customers, and Erroneous Observations**

28. As I explained in the October 2007 Willig Declaration, even if IMS could be used to measure transactions at the TPP level, the data are flawed in a way that dilutes the observed changes in discounts and dispensing fees in response to the alleged scheme. First, the data commingle PBM transactions on behalf of TPPs with Medicaid payments and cash payments from uninsured payers. According to Dr. Hartman, the Medicaid and cash payments received by retail pharmacies are a function of AWP.<sup>24</sup> Second, I pointed out in the October 2007 Willig Declaration that approximately 30 percent of retail pharmacies contributing data to the IMS NPA survey provide AWP rather than actual reimbursement for all three categories of transactions.<sup>25</sup> This flaw in the IMS NPA data further biases down the apparent market response to the alleged scheme.<sup>26</sup> In Appendix 4, I show an example of how these data problems will lead to an overestimate of damages using Dr. Hartman's aggregate damages methodology.

29. The intuition behind these biases, all of which lead to an overstatement of damages, is the following. Suppose the average measure of reimbursement in the IMS data (AA) for any drug includes two types of transactions, both of which are a function of AWP. The first type of transaction contains a mechanism to respond to an artificial increase in AWP (*e.g.*, TPP transactions with renegotiable discounts and dispensing fees), and for this type of transaction, the true average drug price (AA) was \$100 prior to the alleged scheme and \$100 after the alleged

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24. October 2007 Hartman Report, at Attachment D, ¶23.

25. Dr. Hartman apparently does not dispute this point in the October 2007 Hartman Report.

26. To test the potential impact of these biases in the IMS NPA data, I re-ran Dr. Hartman's statistical analysis testing his no "push-back" hypothesis using data from GE and Cigna. I found evidence of "push-back" by TPPs. As I explain below, my results using the GE data are robust to disaggregation between retail pharmacy transactions and mail order transactions.

scheme. In other words, this group of transactions had complete mitigation of the effects of the alleged scheme. The second type of transaction does not contain a response mechanism (*e.g.*, transactions where the pharmacy reports AWP itself, rather than AA or Medicaid transactions that are not part of the class and do not mitigate the change in AWP). For this second type of transaction, the average AA measured in the IMS data was \$100 (like the first TPP group) prior to the alleged scheme, but after the alleged scheme, the average AA increased to \$104. Because Dr. Hartman's data cannot distinguish between these two types of transactions, he calculates an average AA over both groups of \$102, and then incorrectly attributes the \$2.00 change in AA to damages for TPPs.<sup>27</sup> Therefore, even if there is complete mitigation, Dr. Hartman's IMS data will show continuing impact and damages from the alleged scheme.

**C. Dr. Hartman's Statistical Analysis Using IMS Data Is Biased Due to the Limitations of the IMS Data**

30. Dr. Hartman uses a statistical analysis to test his hypothesis that there was no mitigation or "push-back" following implementation of the alleged scheme. With his analysis, Dr. Hartman concludes that there was no significant "push-back." Of course, since the IMS data measure PBM payments, not TPP reimbursements, Dr. Hartman's conclusion from his statistical analysis should be interpreted as a finding of no significant (essentially zero) squeeze of retail pharmacies on the part of PBMs.<sup>28</sup> As I pointed out in the October 2007 Willig Declaration, Dr.

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27. My simple example here assumes that the two transaction groups are equal in size so that the weighted average of the transactions priced at \$104 and the transactions priced at \$100 is equal to \$102, the simple average. My example also assumes that the average prices paid by both groups are equal. These are simplifying assumptions made only for the purposes of this illustration and changing them does not affect the overall result. The actual magnitude of the bias created by Dr. Hartman's use of the IMS data will depend on the prevalence of the biasing transactions in the data and the average prices for those biasing transactions.

28. I note that such a conclusion is contradicted by Dr. McDonough's opinion that PBMs were able to squeeze benefits from retail pharmacies following implementation of the

Hartman's regression model using IMS data and stacking all of the drugs in Dr. Hartman's sample shows a statistically significant negative trend in the ratio AA/AWP.<sup>29</sup> That is, this evidence contradicts Dr. Hartman's conclusion, drawn from 278 separate regressions for each drug, that there is no systematic push-back.<sup>30</sup> The extent of observed "push-back" in the data is small relative to comparable estimates using the GE and Cigna data. This difference is not surprising given the limitations in the IMS data including mis-measurement of TPP transactions and dilution resulting from inclusion of Medicaid transactions, cash transactions and misreporting of AA by retail pharmacies.

**D. Dr. Hartman's Constant Relationship Assumption Permeates His Overall Analysis**

31. Although Dr. Hartman first introduced his constant relationship assumption in the October 2007 Hartman Report, his reliance on this assumption permeates every aspect of his overall analysis. The reason for this is that he needs this assumption in order to justify his claim that his methodology captures any mitigation that occurred in response to the increased AWP/WAC ratio. His IMS data, at best, measure PBM payments to retail pharmacies. He therefore needs the constant relationship assumption in order to claim that any market response at the TPP level immediately translates to an observable market response at the retail level.

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(...continued)

alleged scheme. September 2007 McDonough Report, at p. 13 ("As the PBM industry learned of the change in AWP to WAC ratio, they were able to renegotiate pharmacy contract rates, reducing the prices paid to pharmacies...[a]s the PBM industry renegotiated pharmacy discounts, the differential between the amounts paid to the pharmacy and revenues from the client rose, improving PBM profit margins.")

29. The results from this stacked regression are shown in September 2007 Hartman Report, at Exhibit F.1.a.
30. See Appendix 5 for my discussion of Dr. Hartman's misleading critique of the stacked regression results.

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32. Dr. Hartman then uses the assumption to argue that he has evidence that PBM competition is not “fierce.” According to Dr. Hartman’s argument, his data show minimal or zero mitigation, therefore PBMs must not be competing fiercely for TPP business. However, Dr. Hartman’s argument is circular. The IMS data do not measure TPP reimbursement paid to PBMs. Therefore, he assumes his conclusion when he claims that his data show him the extent of TPP push back in response to increased AWP/WAC ratios. Since he does not observe TPP reimbursements, he cannot validly draw conclusions about the extent of TPP push-back.

33. Furthermore, Dr. Hartman’s constant relationship assumption leads him to conclude that his methodology satisfies the Court’s instruction to provide a “feasible” damages methodology that can account for mitigation through renegotiation and recontracting. By assuming that his data capture all mitigation, Dr. Hartman argues that the Court need not be concerned that his model will overstate damages. This is simply wrong as is recognized in the Court’s instruction that when calculating aggregate class-wide damages, he should account for mitigation occurring as a result of renegotiation or renewal of TPP contracts. Moreover, it bears repeating here that any attempt to evidence Dr. Hartman’s constant relationship assumption would require individualized inquiry into the relationships between each TPP and the PBM with which it works.

### **III. EMPIRICAL EVIDENCE IS CONSISTENT WITH MITIGATION AND RENEGOTIATION, AND DR. HARTMAN’S DAMAGES METHODOLOGY OVERSTATES DAMAGES**

34. In the September 2007 Hartman Report, Dr. Hartman used the IMS data in two distinct analyses. First, he ran a series of regressions across drugs in an attempt to show that there was no statistically significant decline in the ratio AA/AWP after January 2002. From this result, he concludes that there is no evidence of systematic “push-back” on the part of TPPs and



that the Court erred in its instruction to exclude estimates of damages in the periods beyond renegotiation of pre-existing contracts.<sup>31</sup> The second analysis is his actual damages estimation that he describes in Section VI and Attachment F of the September 2007 Hartman Report. That analysis does not rely on his regressions. Instead, he measures damages by computing the percentage change in the ratio AA/WAC for each Appendix A drug in each month in comparison with the average value of AA/WAC in the three months prior to change in the drug's AWP/WAC ratio. For the reasons that I explain below, there are a number of problems with this damages model beyond the use of IMS data that understate the market responses on the part of TPPs.<sup>32</sup>

**A. My Analysis Using GE and Cigna Data Indicate Statistically Significant Market Response at the TPP Level**

35. In the October 2007 Willig Declaration, I addressed the implications of mis-measurement and dilution in the IMS data used by Dr. Hartman and showed the potential bias this creates. As an example of the potential bias, I re-ran Dr. Hartman's statistical analysis that purports to show that there was no statistically significant "push-back" in the TPP contractual terms d and df using data from two TPPs, GE and Cigna.<sup>33</sup> The GE and Cigna data provide a

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31. September 2007 Hartman Report, at ¶5; Hartman Video Tutorial, at p. 2.

32. In the October 2007 Willig Declaration, I addressed the first analysis because it relates directly to the Court's inquiry as to whether any aggregate damages methodology (not just Dr. Hartman's particular damages model) is feasible for providing an estimate of damages that accounts for ending of potential harm after contract renegotiation. I did not address Dr. Hartman's particular damages model other than noting that Dr. Hartman's approach to damages that he has advocated in all of his declarations necessarily leads to an overstatement of aggregate damages because it fails to recognize and account for mitigating market responses.

33. I did not run the GE and Cigna data through Dr. Hartman's aggregate damages model because the inherent biases in the model lead to a meaningless overstatement of the apparent damage. For example, it is hardly surprising that damages are generated when running the aggregate damages model on the GE and Cigna data, given that the aggregate



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way to see what happens with Dr. Hartman's "push-back" analysis when using data that are measuring payments at the TPP level and do not include Medicaid, cash payments and observations where survey respondents provide AWP rather than true reimbursement (AA). Obviously, the GE and Cigna data are not a substitute for a general database covering all TPP transactions because the GE and Cigna data reflect only the reimbursements generated by those two TPPs. These data, however, are useful for examining the implications of the mis-measurement and dilution in Dr. Hartman's IMS data.

36. The analysis of the GE and Cigna data that I presented in the October 2007 Willig Declaration is a test of the particular hypothesis Dr. Hartman puts forth in the September 2007 Hartman Report. Dr. Hartman's hypothesis is that on a drug-by-drug basis there is no statistically significant negative trend in the ratio AA/AWP after January 2002.<sup>34</sup> The results I presented in the October 2007 Willig Declaration show a statistically significant drop in the AA/AWP ratio following January 2002 on a drug-by-drug basis and in aggregate.

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(...continued)

damages model is limited to Appendix A drugs and ignores the offsetting effects of market responses in non-Appendix A drugs. This is a mistake that would lead to a finding of damages even when there is complete mitigation through renegotiation.

34. Dr. Hartman tests this hypothesis on a drug-by-drug basis. Although he finds that only 29-32 percent of the drugs he examined show a negative and statistically significant trend, his stacked model over all drugs that he examined shows a significant negative trend. (September 2007 Hartman Report, at Attachment F, ¶33). In the October 2007 Hartman Report, Dr. Hartman claims that the stacked analysis is inappropriate. (October 2007 Hartman Report, at Attachment D, ¶32). In Appendix 5, I address Dr. Hartman's claim by explaining it is appropriate to stack reimbursement data across drugs to test the hypothesis that there has been overall mitigation across all drugs in the data. More important, I analyze both the drug-by-drug models and the stacked model with the GE and Cigna data and find significant negative trends in AA/AWP under both approaches. (October 2007 Willig Declaration, at ¶¶52-55 and Appendix 4).

37. Dr. Hartman now criticizes the analysis by claiming that I should have separated mail order transactions and retail transactions in the GE and Cigna data in my statistical analysis.<sup>35</sup> In the first place, this criticism is incorrect because Dr. Hartman's own analysis uses results from IMS data that are limited to retail transactions and then extrapolates to mail order transactions, based on the implicit assumption that market responses in retail transactions are similar to market responses in mail order transactions.<sup>36</sup> More importantly, the separation of the GE data into mail order and retail (the Cigna data are already limited to retail) makes virtually no difference in my results and reinforces my finding that there are statistically significant declines in the AA/AWP ratio, consistent with TPP push-back. I present the results of the disaggregated analyses in Table 2.

38. Dr. Hartman presents disaggregated results in Tables 6 and 7 of the October 2007 Hartman Report that are consistent with my analysis in Table 2. However, he does not discuss these results in his text. Rather, he provides a misleading analysis using the GE and Cigna data in his aggregate damages model to claim that damages continue even after renegotiation. The analysis is misleading because the design of Dr. Hartman's damages model, as I now explain, generates damages even when there are none and necessarily overstates damages. Indeed, Dr. Hartman's biased result showing continuing damages after renegotiation in the GE data has

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35. October 2007 Hartman Report, at ¶19. Although Dr. Hartman confuses the issue by claiming that this criticism applies to both the GE and Cigna data, the reality is that the Cigna data are already limited to retail transactions. Dr. Hartman's claim therefore applies only to the GE data.

36. See September 2007 Hartman Report, at Notes to Exhibit F.3. ("IMS does not track dollars to the mail order retail channel. In order to capture the purchases of the Class through mail order, the following adjustment to damages was made. The percentage of sales to mail order with respect to all other retail channels was calculated. The resulting adjustment to damages would then be one divided by one minus the mail order percentage.")

nothing to do with the disaggregation of the data into mail order and retail. The result is the same even with the data aggregated to combine mail order and retail.

39. Dr. Hartman admits that the evidence I presented with the GE data, regardless of whether they are disaggregated into mail order and retail, indicates renegotiation in July 2003.<sup>37</sup> Nevertheless, Dr. Hartman finds what he believes to be continuing impact from the alleged scheme beyond July 2003. As I now explain, there are two principal sources of bias in Dr. Hartman's damages model that lead to the spurious appearance of continuing damages after renegotiation. These two sources of bias result from the model's inability to measure the full magnitude and complexity of the market responses to the increased AWP/WAC ratio.

**B. The Hartman Aggregate Damages Model Necessarily Overstates Damages by Ignoring Non-Appendix A Drugs**

40. Using the GE data, Dr. Hartman admits that GE appears to have renegotiated in July 2003. Yet Dr. Hartman uses his damages model to find what he believes to be continuing harm beyond July 2003 and running through the end of his damages period. For this reason, he concludes that the Court should not limit damages to the period before renegotiation for each TPP.<sup>38</sup> Examination of Dr. Hartman's methodology should lead the Court to reject Dr. Hartman's conclusion and stand by the position that his model is incapable of measuring damages following renegotiation.

41. Dr. Hartman's damages model is limited to Appendix A drugs (*i.e.*, the drugs that experienced an increase in the AWP/WAC ratio during the Class Period) and "measures" damages for each of those drugs only in the period following the change in each drug's

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37. October 2007 Hartman Report, at ¶¶18, 20.

38. October 2007 Hartman Report, at ¶20; Hartman Video Tutorial, at p. 15.

AWP/WAC ratio. The incongruity is that when renegotiation occurs, changes in contractual terms such as the discount off AWP and the dispensing fee apply to all drugs, not just Appendix A drugs.<sup>39</sup> This is a plain fact. When PBMs and TPPs negotiate their contracts, they do not distinguish between groups of drugs on the basis of the AWP/WAC ratio. Instead, they negotiate contract terms across all self-administered brand name prescription drugs. There is no dispute that contractual terms apply across-the-board to virtually all self-administered brand name prescription drugs. So, when the parties renegotiate the discount or the dispensing fee, they recognize that the changes in those parameters apply to all drugs, not just the drugs that experienced an increase in the AWP/WAC ratio. Accordingly, a mitigating parameter change such as an increase in the discount does not need to be large enough to offset the increased cost when applied only to Appendix A drugs. Instead, the increased discount would be applied to all drugs -- those that experienced an increase in the AWP/WAC ratio and those that did not -- and on that basis offset (or more) the increased cost.

42. Dr. Hartman's analysis, however, fails to recognize what would be clear to the TPP and PBM involved in the renegotiation. Instead, Dr. Hartman's analysis assumes that if a fully mitigating renegotiation occurs, it must be fully mitigating in the two parameters he measures (discount and dispensing fee) for each Appendix A drug. The problem is that such a renegotiation would never happen because it would create a windfall for the TPP on all drugs that did not experience an increase in the AWP/WAC ratio (*i.e.*, all non-Appendix A drugs). For example, if the parties agreed to, say, a one percentage point increase in the discount off AWP in the renegotiation, that one percentage point increase would apply to drugs that did not experience

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39. For purposes of the analysis in this section, I ignore that Dr. Hartman's model at best captures changes in only two (discount and dispensing fee) of a number of contractual and non-contractual terms and parameters that can change as a result of a market response to the change in the AWP/WAC ratio. I address this further shortcoming of his aggregate damages model in the next section.

an increase in the AWP/WAC ratio. For those drugs, the TPP's ingredient cost would fall. So, to make the TPP whole following the alleged artificial increase in AWP for some drugs, it would negotiate an increase in the discount sufficient to put its total ingredient cost over all drugs back to its equilibrium level. Such an agreement means that ingredient cost on Appendix A drugs will continue to be elevated above their "but-for" level, while ingredient cost for non-Appendix A drugs will be below their "but-for" level. In aggregate, the total ingredient cost would be at its "but-for" level. In this situation, with complete mitigation following renegotiation, Dr. Hartman would find continuing damages because he incorrectly focuses only on Appendix A drugs.

43. Thus, it is hardly surprising that Dr. Hartman finds continuing harm using the GE data in his damage model because the model ignores a number of implications of renegotiation, one of which is that renegotiation of contractual terms applies to all drugs, not just the drugs experiencing an artificial increase in AWP (*i.e.*, Appendix A drugs). I now turn to another important implication of renegotiation and market responses in general. Market responses either through contract renegotiation or changes in behavior of parties such as manufacturers, TPPs and consumers, lead to complex mitigation in parameters other than the discount and dispensing fee. Dr. Hartman's aggregate damages model, however, cannot capture the impact of these changes and therefore necessarily overstates damages.

**C. The Hartman Aggregate Damages Model Necessarily Overstates Damages by Ignoring Changes in Parameters Other than Discount and Dispensing Fee**

44. In the October 2007 Hartman Declaration, Dr. Hartman attempts to explain how his aggregate damages methodology using the IMS data captures all of the potential market responses that I identified in my previous report and declarations.<sup>40</sup> Examination of Dr.

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40. October 2007 Hartman Report, at ¶30; Hartman Video Tutorial, at p. 2. See January 2007 Willig Report at ¶¶48-50, 78-89, 93-99, 101-104; May 2007 Willig Declaration at ¶¶29-37; October 2007 Willig Declaration at ¶¶35-37.

Hartman's arguments shows that they are incorrect. His model, at most, captures only changes in discounts and dispensing fees, and even changes in those two parameters are mis-measured because his IMS data capture retail transactions, not TPP-level transactions. I now address each of Dr. Hartman's claims regarding how his model captures the effect of changes in all relevant parameters is in error.

45. **Discount:** Dr. Hartman claims that any changes in the discounts in TPP contracts "will be reflected immediately in the amounts paid by TPPs at retail." This is an inapposite comment since TPPs generally pay PBMs and do not pay retail pharmacies directly with their reimbursements. As I discussed earlier, Dr. Hartman's methodology may capture some changes in some discounts, but not the discounts contained in TPP contracts with PBMs. Instead, the discounts partially captured in Dr. Hartman's analysis are the discounts contained in the PBM contracts with retail pharmacies.

46. **Dispensing Fees and Other Fees:** The analysis of dispensing fees is analogous to the analysis of discounts. Dr. Hartman's analysis captures dispensing fees measured at the PBM/retail pharmacy level, not the TPP/PBM level. Regarding other fees, Dr. Hartman claims it is unclear what the other fees could be. There are a number of other fees routinely determined in TPP contracts with PBMs, such as administrative fees, audit fees and utilization management fees.<sup>41</sup> Dr. Hartman relies on a tautology when he claims, "If the other fees are reflected in reimbursement rates (AA) at retail, they are included in the IMS data and reflected in the damage calculation." The problem is that these fees are not captured in the PBM contracts with retail pharmacies and therefore are not reflected in the transactions that are the basis for the IMS data

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41. See, for example, Exhibit A to the May 2002 contract between Express Scripts, Inc. and Philadelphia Federation of Teachers Health and Welfare Fund. (ESI-277-00003887-3918).

used by Dr. Hartman. Consequently, Dr. Hartman's analysis cannot capture any changes in these fees that may result from renegotiation.

47. **Rebate Pass-Through Percentage:** Dr. Hartman admits that this figure, which is routinely contained within TPP contracts with PBMs, is not captured in the IMS data. That is, when a TPP receives a payment from the PBM pursuant to an agreement to split (at some negotiated percentage) the PBM's rebate dollars, that transaction is not captured in the IMS data.<sup>42</sup> This is a shortcoming of Dr. Hartman's model that he addresses, without fixing. Instead, Dr. Hartman attempts to deflect this shortcoming in his model and data by claiming that he applies a percentage reduction of 2.7 percent to his damages estimates to account for rebates.<sup>43</sup> As I explained in the January 2007 Willig Report, Dr. Hartman's rebate adjustment relies on the unsupported assumption that rebate amounts received by TPPs remain a fixed percentage of AWP after the alleged scheme.<sup>44</sup> The problem is that Dr. Hartman's 2.7 percent adjustment is meant to account only for increased rebates received by TPPs in proportion to the rise in AWP. This has nothing to do with increases in the rebate pass-through percentage, which would

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42. See McDonough Article, at p. 274, for a discussion of the many ways in which PBMs pass rebate dollars on to TPP clients. ("Rebate allocations are based on a wide variety of criteria, depending on the terms of the contract between the PBM and its clients. In some cases, the PBM may pay a basic guaranteed rebate amount on a per-claim basis. Other contracts call for a sharing of percentage of the rebates that are received, with the PBM retaining 10 percent to 20 percent of the rebate as an administrative fee. Express Scripts offers a 'big grid' system that provides a predetermined level of rebate, depending on formulary and benefit decisions that are chosen by the client. PBMs may use rebate revenues to lower administrative fees or other costs that are paid by the client. In some cases, PBMs use rebate revenues to buy down the cost of the medication or pharmacy dispensing fees that are charged to their clients.")

43. September 2007 Hartman Report, Attachment F, at ¶¶60-61.

44. January 2007 Willig Report, at ¶¶121-123. Although I explained this point in the January 2007 Willig Report, Dr. Hartman has declined to challenge the analysis in each of his declarations since January 2007.



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increase rebates received by TPPs in a greater proportion than the rise in AWP. In other words, Dr. Hartman's adjustment assumes that rebates received remain a fixed proportion of AWP, but the increase in rebate pass-through percentage for any TPP means that rebates received by the TPP relative to AWP will increase.

48. Dr. Hartman's error here is that even a modest increase in the negotiated rebate pass-through percentage will increase the dollar amount of the rebate received by the TPP as a percentage of AWP. This will cause Dr. Hartman's model to overstate damages even with his adjustment that assumes a fixed relationship between rebates received by TPPs and AWP.

49. **Risk-Sharing Terms:** Dr. Hartman claims that his model captures these terms because he assumes that they are reflected in changes in discount and dispensing fee. He is incorrect for two reasons. First, risk-sharing terms that affect discount and dispensing fee affect those parameters in the TPP/PBM contracts, not the PBM contracts with retail pharmacies. Second, risk-sharing terms often trigger rebates or side payments between PBMs and TPPs that would not be captured in the retail transactions that are the basis for the IMS data.

50. **Co-Pay Terms and Plan Design:** Here Dr. Hartman gives an inapposite response that has nothing to do with these contractual terms when he states, "To the extent that drug benefit plans are renegotiated to alter the discount off AWP, the dispensing fee and/or formulary placement, the relevant aspects of those renegotiations are reflected in the calculated amount allowed to be paid by the TPP (AA) at retail..."<sup>45</sup> This response completely misses the point. Changes in co-pay terms and plan design are changes in the sharing of cost between the TPP and the TPP's members. If changes in these terms occur, there will be no necessary reflection of these changes in the IMS data.

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45. October 2007 Hartman Report, at ¶30.



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51. **WAC:** Dr. Hartman claims that his model accounts for changes in WAC by measuring harm as a percentage change in the reimbursement per dollar of WAC (AA/WAC) for each drug. This response reflects a fundamental mistake in Dr. Hartman's economic analysis and damages methodology. Dr. Hartman's methodology controls for observed changes in actual WAC which is always increasing over time. He ignores the problem that the alleged scheme, by increasing the AWP/WAC ratio, may have caused manufacturers to slow the growth of WAC, causing the observed actual WAC for any drug at any point in time to be lower than the level of WAC that would have prevailed but for the alleged scheme. This is a fundamental economic point that Dr. Hartman fails to consider, but is reflected in the evidence regarding manufacturers' reactions to the alleged scheme.<sup>46</sup>

52. The economic problem with Dr. Hartman's analysis is the following: Manufacturers, like any firm, set prices (*i.e.*, WAC and rebates) to maximize profit. When setting these prices they seek to generate what they consider to be the optimal quantity demanded from consumers and their agents, including TPPs. According to plaintiffs, the alleged scheme increased the AWP/WAC ratio on Appendix A drugs which in the first instance caused an artificial increase in AWP and therefore AA for those drugs. Basic economic theory holds that an increase in price, in this case AA, causes a reduction in the quantity demanded.<sup>47</sup> The reduction in quantity demanded then translates directly to a loss in revenue and profit for the

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46. Chris Macinski wrote in an email to Ryan Soderstrom on March 28, 2002, [REDACTED] (ESI-414-00001762). See also an Astra Zeneca presentation titled, "Price Action Recommendation:" November 19, 2002 (AZ0468041-91) in which Erik Schultz, Pricing Strategy Manager [REDACTED]

47. The precise amount of the reduction in the quantity demanded depends on the elasticity of demand for the drug, which in turn depends on the degree of substitutability with other drugs or therapies.

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manufacturer relative to the level of revenue and profit that would have been earned absent the unexpected increase in the AWP/WAC ratio.

53. This is a plausible explanation for the complaints by manufacturers that arose once they understood that the AWP/WAC ratios reported by FDB increased. Dr. Hartman cites these complaints, but fails to consider that the manufacturers had recourse. They could adjust down the growth in WAC, or they could increase the rebates granted to PBMs. The manufacturers' responses would have been on a drug-by-drug basis and would not likely entail a reduction in WAC, only a reduction in the growth in WAC.

54. The implication of this analysis for Dr. Hartman's model is that the observed WACs that are rising over time are likely not the levels of WAC that would have prevailed but for the alleged scheme. The "but-for" levels of WAC would likely have been higher. Dr. Hartman's model overstates damages in all periods for any drug in which there was a modification in the growth of WAC. Indeed, if a manufacturer adjusted WAC sufficiently to offset any harm to the TPP from the increased AWP/WAC ratio (*i.e.*, by 4.17 percent), Dr. Hartman's model would generate positive damages for that drug. See, Appendix 6.

55. In summary, by ignoring each of these mechanisms that mitigated to varying degrees the impact of the alleged scheme on TPP reimbursements, Dr. Hartman's damages methodology necessarily overstates damages. Dr. Hartman is incorrect when he argues that his model generates the average damages. His model actually generates over-stated damages because the factors it ignores all cut in the direction of reducing damages. This bias is the reason that the model is not feasible for determining aggregate damages regardless of the length of the class period.

**IV. DR. HARTMAN'S NEW THEORY OF LIMITED COMPETITION AMONG PBMS IMPLIES THAT TPPS WILL DIFFER IN THEIR MARKET RESPONSES TO THE ALLEGED SCHEME**

56. In the October 2007 Hartman Report, Dr. Hartman appears to have modified his opinion regarding PBM competition. In his previous declaration, Dr. Hartman relied on the argument that PBMs benefited from the alleged scheme through the increased profit at their captive mail order operations. According to Dr. Hartman, these PBMs would not have passed on information to their clients regarding the increased AWP mark-ups, nor would they have shared the benefit with TPPs through changes in contractual terms because such actions would be against the interests of the PBMs.<sup>48</sup> Dr. Hartman now acknowledges that there is competition among PBMs, but holds that this competition is “constrained” or “nuanced,” rather than “fierce.” Dr. Hartman acknowledges that this position directly contradicts the Court’s findings and Dr. Berndt’s conclusions.<sup>49</sup>

57. Dr. Hartman continues to confuse “vigorous” or “fierce” competition with perfect competition.<sup>50</sup> Perfect competition is not necessary for there to be mitigation of the impact of the alleged scheme. Instead, any mitigation caused by competition makes the determination of damages an individualized fact question. Dr. Hartman now admits that given the limited competition among PBMs, the determination of whether there was mitigation is an empirical question.<sup>51</sup> The problem is that Dr. Hartman relies on his flawed analysis of the IMS data to

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48. September 2007 Hartman Report, at ¶63; Hartman Video Tutorial, at p. 2, 6.

49. Class Certification Order, at 4. Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005, at ¶205.

50. October 2007 Hartman Report, at ¶¶44-45; Hartman Video Tutorial, at pp. 2-3.

51. October 2007 Hartman Report, at Attachment D, ¶15-16. In my previous report and declarations, I have argued that determination of the degree of mitigation for each TPP is an empirical question. January 2007 Willig Report, at ¶77; May 2007 Willig Declaration, at ¶9; October 2007 Willig Declaration, at ¶¶11-13. Dr. Hartman, however, continues to mischaracterize my position when he claims that my position is that there is complete

claim that there has been virtually no “push-back” or mitigation on the part of TPPs.<sup>52</sup> As I have explained above, limitations of Dr. Hartman’s data and his methodology imply that he would not be able to determine whether there had been mitigation on the part of TPPs even if there had been complete mitigation. His data do not measure the market responses from TPPs and the design of his model would find damages even when there are none.

58. Dr. Hartman now concedes that two PBMs, ESI and Caremark, which together account for 17 percent of expenditures processed by PBMs, knew of the impacts of the alleged scheme. He then minimizes this concession by claiming that there is “no evidence that ESI or Caremark systematically or even selectively improved TPP reimbursement contracts, based on the knowledge of the increased mark-ups.”<sup>53</sup> Rather, the significant point here is that the evidence from Caremark and ESI are examples that prove that individualized analysis is required to determine the existence and the extent of harm to any TPP. According to Dr. Hartman, these two large PBMs knew of the implications of the alleged scheme. As I explained in the January 2007 Willig Report and the May 2007 Willig Declaration, market responses occur because the parties respond to increased list prices (*i.e.*, AWP) through increased discounts and other concessions. This is an ongoing process in the market that does not require specific knowledge of the alleged scheme or even of the increased AWP/WAC ratio. That said, the fact that two large PBMs apparently were aware of the increased mark-up, coupled with the evidence from

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(...continued)

recoupment and zero impact from the alleged scheme. October 2007 Hartman Report, at Attachment D, ¶¶4-8.

52. October 2007 Hartman Report, at ¶48 (“We simply do not find evidence of any meaningful mitigation”); Hartman Video Tutorial, at p. 15.

53. October 2007 Hartman Report, at ¶43; Hartman Video Tutorial, at p. 4.

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market participants such as Dr. McDonough that were aware of the increased mark-up,<sup>54</sup> makes it implausible to believe that there were no market responses impacting TPP reimbursements. Furthermore, Dr. Hartman acknowledges that a number of PBMs are vertically integrated into the retail and mail order pharmacy businesses. Yet Dr. Hartman ignores this source of PBM knowledge regarding changes in the mark-up of AWP over WAC.

59. It is incongruous that Dr. Hartman continues to claim that the lack of fierce or vigorous competition among PBMs for TPP business kept PBMs from passing on any benefit received from the alleged scheme at the same time that he now puts forth an argument of constant or zero profit margin for PBMs on TPP transactions. I understand that Dr. Hartman needs the latter argument to resurrect his use of IMS data based on retail transactions as a meaningful data source to “measure” TPP reimbursements. Dr. Hartman’s need to rely on the IMS data, however, leads here to inconsistent theories. Dr. Hartman must decide whether he believes that PBMs do not compete and therefore earned higher profit margins on TPP transactions following implementation of the alleged scheme, or whether he believes that there is vigorous competition that would force them to compete away any of the benefits from the alleged scheme. He cannot have it both ways.

**V. DR. HARTMAN’S DAMAGES METHODOLOGY DOES NOT SATISFY THE COURT’S INSTRUCTION**

60. In the October 2007 Willig Declaration, I showed that Dr. Hartman’s damages methodology does not satisfy the Court’s instruction. The Court’s view of Dr. Hartman’s damages methodology was very clear:

Dr. Hartman’s methodology for calculating aggregate damages would lead to a significant overstatement because it fails to consider key provisions in contracts that are

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54. See September 2007 McDonough Report, at pp.11-12.

renegotiated and renewed.<sup>55</sup>

Based on this view the Court then issued the following instruction:

I am not persuaded that the aggregate methodology works with respect to the proposed class of TPPs. As I understand the methodology, it includes contracts that were renegotiated after the large bump-up in early 2002. Dr. Hartman may submit an aggregate damage methodology which includes only those contracts in effect when the scheme took place and excludes reimbursements under contracts renegotiated in response to the increase. Another alternative would be to only include damages for one year after the large increase in 2002 took effect.<sup>56</sup>

61. In the October 2007 Hartman Declaration, Dr. Hartman fails to satisfy the Court's instruction. First, Dr. Hartman admits that he cannot satisfy the Court's first alternative. Dr. Hartman states, "There is no data base that would allow me to identify and exclude on a Class-wide basis those contracts that were 'renegotiated in response to the increase.'"<sup>57</sup> Dr. Hartman's admission does not mean he does not have to satisfy the Court's instruction. It simply means that he acknowledges that the Court should not certify a TPP class for aggregate damages if the Court seeks to avoid inclusion of damages after renegotiation or contract renewal. The lack of class-wide data to determine the renegotiation dates is one determinative reason why assessment of the appropriate damages for each TPP requires an individualized analysis.

62. This leaves the second alternative. Dr. Hartman does nothing to prove that he can determine the appropriate length of time to cut off the damages calculation in order to avoid overstatement of damages. Instead, he simply repeats his claim that he satisfies the Court by letting the Court decide when to end his damages calculation. Dr. Hartman states, "If the only alternative that the Court offers is to calculate 'damages for one year after the large increase in

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55. Class Certification Order, at p. 24.

56. Class Certification Order, at p. 25.

57. October 2007 Hartman Report, at ¶34.

2002 took effect,' I can do so and have done so. I have presented that calculation in Table 3 of my September 2007 Report; I discuss the calculation in ¶¶70-73 therein."<sup>58</sup> The disabling problem with this claim is that it does not satisfy the Court's instruction.

63. Dr. Hartman's response to the Court's instruction is to offer essentially the same model that does not account for the effects of mitigation and has already been found to be unacceptable by the Court. As I have shown below and in my other declarations and report, Dr. Hartman's model overstates damages for any period of time, whether it be 3.5 years, two years, one year or six months.

64. Dr. Hartman seeks to shift the burden from himself to the Court to determine when to cut off the damages model to obtain an appropriate damages figure. Without data to determine the appropriate period of time, Dr. Hartman provides no useful information to the Court to determine the appropriate amount of damages. This is a shortcoming of Dr. Hartman's methodology that is not solved by providing the damages measure on a monthly or annual basis.

#### **VI. DR. HARTMAN'S AGGREGATE DAMAGES MODEL CANNOT BE USED TO DETERMINE DAMAGES FOR THE PERCENTAGE CO-PAY CONSUMER CLASS**

65. Dr. Hartman and I agree that the members of the percentage co-pay consumer class pay a percentage of the contractual rate negotiated by their TPP. Therefore, they pay  $c(AWP(1 - d) + df)$ , where  $c < 1$  is the pre-determined percentage co-pay. They do not pay a straight percentage of AWP. Where Dr. Hartman and I disagree is on how these aggregate damages can be estimated. The co-pay damages are a percentage of the TPP damages. Therefore, they are derivative of the TPP damage. Accordingly, the co-pays' damages will depend on the individual characteristics of the TPPs to which these consumers subscribe. As the

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58. October 2007 Hartman Report, at ¶34.

estimation of aggregate damages for the TPPs is a complicated task, that must be undertaken with an individualized TPP-by-TPP analysis, so is the estimation of damages for the class of consumers who pay a percentage co-pay.

66. In contrast, Dr. Hartman believes that the aggregate damages for this consumer class are merely a percentage of the aggregate TPP damages that he estimates using his model. However, I have shown in Section III why his aggregate damages model necessarily overstates damages and will find damages for TPPs (and in this case consumers) even when there are none. The fatal flaws in Dr. Hartman's aggregate TPP damages model also infect any measure of aggregate damages for the consumer class that are based on his TPP model. Therefore, Dr. Hartman has not presented an acceptable aggregate damages model for this consumer class.

## **VI. CONCLUSION**

67. In the October 2007 Hartman Report, Dr. Hartman defends his use of IMS data in his aggregate damages methodology by asserting his constant relationship assumption. Dr. Hartman relies on this assumption to claim that the measurement of PBM payments to retail pharmacies in the IMS data is the "functional equivalent" of measuring TPP reimbursements. Dr. Hartman then uses this assumption to claim that his model captures whatever mitigation occurs at the TPP level and therefore provides a feasible measure of damages that satisfies the Court's instruction.

68. Dr. Hartman's constant relationship assumption is not supported by economic theory or empirical evidence. Moreover, the assumption contradicts Dr. Hartman's opinions regarding limited competition among PBMs for TPP business.

69. In addition, Dr. Hartman's damages methodology overstates damages because it ignores the implications of mitigation and renegotiation. In particular, the model does not account for the offsetting mitigation applied to non-Appendix A drugs. Furthermore, the model



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ignores all mitigating parameters other than the discount off AWP and the dispensing fee, and even those parameters are mis-measured because the IMS data do not capture TPP reimbursements.

70. Dr. Hartman's claim of limited competition among PBMs does not prove that PBMs failed to pass on the benefits stemming from the increased AWP/WAC ratio to TPPs. Instead, Dr. Hartman's position on PBM competition suggests that determination of impact on TPPs requires an individualized analysis. This is the position that I have taken in each of my previous declarations and report.

71. Rather than responding to the Court's instruction to provide a feasible damages methodology, Dr. Hartman admits that there are no data that would enable him to comply with the Court's instruction, and then continues to advocate the use of his aggregate damages methodology that by its very design overstates damages in each period.

72. Finally, because aggregate damages for the consumer co-pay class are derivative of aggregate damages for the TPP class, all the biases and errors in Dr. Hartman's aggregate damages methodology for the TPP class apply to the determination of damages for the consumer co-pay class.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 8<sup>th</sup> day of November 2007, in Princeton, New Jersey.

Robert Willy

Table 1

**Analysis of the 50 Publications Cited in Hartman Attachment B**

<b>Category</b>	<b>Number of Publications</b>
Does not use any IMS revenue or price data	13
Does not use IMS retail revenue or price data for branded drugs	29
Uses IMS retail revenue or price data for branded drugs <sup>1</sup>	8
<b>Uses IMS data to determine TPP payments to PBMs</b>	<b>0</b>
Total	50

<sup>1</sup>In a few of the articles, there are references to payments by third-party payors, but the context clearly indicates that they are considering both PBMs and other third-party payors as "TPP"s.

Table 2

## Summary of Fully Interacted Regressions

### GE Group Assurance Life

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## **APPENDIX 1**

## **APPENDIX 1**

### **Additional Materials Relied Upon**

1. Report of Raymond S. Hartman Regarding Aggregate Damages and report backup documents, data, and programs (October 29, 2007).
2. Tutorial Presentation and Demonstratives of Dr. Raymond S. Hartman (October 29, 2007).
3. Rebuttal Report of Dr. Kimberly P. McDonough and report backup materials (October 29, 2007)
4. Tutorial Presentation and Demonstratives of Dr. Kimberly McDonough (October 29, 2007)
5. Declaration of Darrell Philpot of IMS Health Incorporated, October 15, 2007.
6. Stephen W. Schondelmeyer and Marion V. Wrobel, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," Final Report, Abt Associates Inc., Prepared for Centers for Medicare and Medicaid Services, August 30, 2004, p. 13

## **APPENDIX 2**

## APPENDIX 2

### Comments on October 2007 Rebuttal Report of Kimberly McDonough

#### I. DR. MCDONOUGH MISREADS MY OPINION REGARDING PLAINTIFFS' CONTRACTS

1. Dr. McDonough states that I indicated that five of the twelve contracts submitted in this case had contract lengths of three years and she suggests in footnote 1 that my review of plaintiffs' contracts differed from Mr. Flum's.<sup>1</sup> However, my report stated that five of the twelve contracts had "initial terms that were **less than** three years."<sup>2</sup> There is no inconsistency between my review of plaintiffs' contracts and Mr. Flum's. Further, Dr. McDonough does not address in her rebuttal report the basic point that I made with these twelve contracts. Namely, she does not address the fact that 41 percent (five of twelve) of the contracts produced by the representative plaintiffs' in this matter do not conform to her opinion that contracts are "[o]verwhelmingly" written for a period of three years.<sup>3</sup> Instead, Dr. McDonough merely explains that her unsubstantiated opinion about contract lengths is based on her personal experience in PBM-TPP contracting.

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1. October 2007 McDonough Rebuttal Report, p. 1.

2. October 2007 Willig Reply, Appendix 2 at ¶2 (emphasis added).

3. September 2007 McDonough Report, at p. 10.



- 2 -

**II. DR. MCDONOUGH'S ARGUMENTS ABOUT THE TIME NECESSARY FOR A TPP TO CHANGE PBMS ARE NOT RELEVANT TO THE ISSUES HERE**

2. Dr. McDonough opines that it would take a year for a TPP to search for and put into place a new PBM contract. She states that, “[i]t commonly takes four to six months to draft and issue RFPs, evaluate the responses and choose the best candidate among the responding PBMs. It would then take several more months for a TPP to convert to a new PBM. Thus, a TPP that desired better contract rates would still need a year to search for, locate, negotiate with and change over to a new PBM.”<sup>4</sup> She suggests that this is a reason why TPPs would not have been able to renegotiate contracts with PBMs. What Dr. McDonough fails to consider is that the relevant question is whether TPPs are able to credibly threaten to change PBMs. It is that threat that will provide the incentive for PBMs to renegotiate new contracts and lower prices for TPPs facing increasing drug inflation.

**III. EVIDENCE OF MID-TERM CONTRACT RENEGOTIATION CONFLICTS WITH DR. MCDONOUGH'S OPINIONS**

3. Dr. McDonough states that “both parties would have to agree to open [PBM-TPP contract] negotiations in the middle of the contract period and that PBMs had, “no financial incentive” to do so.”<sup>5</sup> This comment reflects a misunderstanding of basic economics. Competition often forces firms to take actions that lower their profit (*e.g.*, reducing prices to meet competition). Firms therefore often engage in such conduct when it may superficially appear that they have “no financial incentive” to engage in the conduct.

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4. October 2007 McDonough Rebuttal Report, p. 2.

5. October 2007 McDonough Rebuttal Report, p. 2.

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4. Dr. McDonough also states that mid-contract renegotiations may involve an RFP and that these negotiations take time; potentially as much time as would be required to negotiate a new contract, which she opines could be a year.<sup>6</sup> However, Dr. McDonough does not comment on the evidence with regard to Express Scripts (“ESI”) and District Council 37 (“DC 37”). As shown in the October 2007 Willig Declaration, ESI and DC 37 did exactly what Dr. McDonough says does not happen in the industry.<sup>7</sup> Namely, ESI, having “no financial incentive” to do so, renegotiated mail order discounts with DC37; lowering mail order prices for DC 37 in the middle of DC 37’s contract term.

5. Dr. McDonough’s opinions regarding the incentives of PBMs to renegotiate contracts with TPPs are not consistent with economic theory. PBMs have the incentive to retain TPP clients because an increased number of clients allows PBMs to negotiate better retail rates with pharmacies, by promising more business for the pharmacy; and having more TPP clients increases volume of sales made by the PBM through in-house mail order pharmacies. Put differently, an increase in the number of PBM clients will increase the profits of the PBM.

6. Dr. McDonough also states that ESI has asked TPPs to renegotiate discounts (to a lower level) in the event of a lowering of the AWP/WAC ratio as a result of the potential FDB settlement in this matter. Dr. McDonough further opines that ESI is asking for this change in contract terms from TPPs even when it did not offer better contract terms following the start of the alleged scheme.<sup>8</sup> Dr. McDonough states this

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6. October 2007 McDonough Rebuttal Report, p. 2-3.

7. October 2007 Willig Declaration, at Appendix 3, ¶¶11-13.

8. October 2007 McDonough Rebuttal Report, p. 3.

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opinion without any evidence and, in fact, there is evidence in this matter that directly contradicts her statement. As mentioned above, ESI renegotiated rates with DC 37 in the middle of contract period after the start of the alleged scheme.

**IV. DR. MCDONOUGH STATES THAT HER CLIENTS WERE NOT FOCUSED ON PHARMACEUTICAL PRICES IN 2002 AND 2003**

7. Dr. McDonough, “saw no increase in the number of TPPs wanting to renegotiate or change PBMs during 2002 or 2003.”<sup>9</sup> She further states that, “[a]s a matter of practical items, most TPPs were working on HIPAA compliance in 2002 and 2003 and resources for other pharmacy initiative were not often available.”<sup>10</sup> Dr. McDonough’s experience with her clients in 2002 and 2003 suggests that they did not make her aware of any action they might have taken to mitigate the effects of the alleged scheme.<sup>11</sup> She further states that some of her clients had chosen to focus their resources on issues related to HIPAA compliance and therefore may not have focused their resources on negotiating new pharmaceutical rates. Her experience is at odds with the empirical evidence that TPPs did mitigate the effects of the scheme.<sup>12</sup> This is another example of the different experiences of the various TPPs and the need for an individualized analysis of impact and damages.

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9. October 2007 McDonough Rebuttal Report, p. 3.

10. October 2007 McDonough Rebuttal Report, p. 3.

11. Dr. McDonough makes similar statements about her clients in the McDonough Video Tutorial where she says that, “not a single one of [her] clients got any kind of reimbursement or back payment from any PBM...” (McDonough Video Tutorial, at p. 6).

12. See, for example, my evidence of mitigation by GE and Cigna.

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**V. THE ROLE OF CONTRACTING CONSULTANTS AND THE ABILITY OF TPPS TO MITIGATE THE EFFECTS OF THE SCHEME RETROACTIVELY**

8. Dr. McDonough states that in light of ESI's request to renegotiate lower discounts in the event of the FDB settlement, several of Dr. McDonough's clients have requested that her firm evaluate current AWP/WAC ratios compared to ratios in 2001 and determine whether AWP discounts currently offered by the client's PBM "sufficiently offset the AWP price increases incurred as a result of the change in AWP to WAC ratio at issue in this case."<sup>13</sup> Dr. McDonough does not provide any detail about how her firm conducts these analyses. Her description suggests that her firm has attempted to evaluate the impact of the alleged scheme and subsequent mitigation undertaken by her clients.<sup>14</sup>

9. This is an example of how TPPs, even potentially small TPPs, can use the services of consulting companies such as Dr. McDonough's to protect themselves from changes in pharmaceutical pricing policies. This is a clear example of how TPPs can retroactively mitigate the effects of the scheme. Further, this is evidence supporting my point that impact and damages in this case cannot be evaluated without an individual, TPP-by-TPP analysis because some TPPs have taken steps to mitigate the effects of the alleged scheme, and have done so retroactively. The aggregate damage model currently proposed by Dr. Hartman will not capture such mitigation and will, therefore, necessarily overstate aggregate damages.

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13. October 2007 McDonough Rebuttal Report, pp. 3-4.

14. Dr. McDonough offers no detail as to how her firm conducted these analyses. However, Dr. McDonough's firm would have had to utilize client claims data for both affected and unaffected drugs in addition to using the FDB pricing data that Dr. McDonough specifically mentions.

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**VI. DR. MCDONOUGH MISCHARACTERIZES MY OPINION  
REGARDING TPP MITIGATION**

10. In the October 2007 McDonough Report, Dr. McDonough states that my opinion regarding the ability of TPPs to mitigate the effects of the alleged scheme is naïve. She states:

Mr. Willing [sic] suggests that TPPs are able to use formularies, tiered copays, and utilization controls to completely offset the increased AWP costs incurred as a result in the change in AWP to WAC ratio. This position is naïve and is contradicted by what I have seen in over 17 years in the managed care industry. If a TPP were able to unilaterally adjust contract terms to compensate for price increases, pharmacy benefit cost inflation would have been non-existent for the past 17 years.<sup>15</sup>

First, my opinion was not that all TPPs would be able to use changes in formularies, co-pays and utilization controls to offset all effects of the alleged scheme, as Dr.

McDonough's comments suggest. Dr. McDonough also says, "Dr. Willig suggests that the AWP price increases could have been completely offset by the drug management tools indicated above."<sup>16</sup> I never suggested that complete offsets occurred for all TPPs. I suggested that these types of TPP responses, which do happen and do mitigate the effects of the alleged scheme, create an individualized issue that must be examined on a TPP-by-TPP basis.

11. Second, Dr. McDonough's suggestion that if TPPs could "unilaterally adjust contract terms" then there would be no pharmacy benefit cost inflation is not correct as a matter of economics or logic. These types of plan design programs are not intended to keep pharmaceutical expenditures constant in the face of increasing costs and

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15. October 2007 McDonough Rebuttal Report, p. 4.

16. October 2007 McDonough Rebuttal Report, at p. 5.

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utilization. These plan design programs are designed to influence demand for pharmaceutical products by steering patients to certain drugs and sharing costs with consumers. These programs are a mechanism by which TPPs keep their expenditures at or near competitive levels. These programs allow a TPP to have some control over which products are preferred for their consumers, which in turn can impact the rebates a TPP receives and therefore the net reimbursement a TPP pays. These programs also shift costs to consumers, which lowers TPP expenditures directly by shifting costs to consumers and indirectly by affecting consumer demand for branded drug products. These programs are not designed to, nor has anyone asserted they are capable of, completely negating natural pharmaceutical price inflation. Dr. McDonough acknowledges all of this in page 4 of her Rebuttal Report:

In fact, while drug management tools help to slow the trend of inflation in pharmacy benefits, they do not completely offset this trend. For example, a TPP could have theoretically raised the copay of Neurontin and Lipitor in response to the AWP changes that occurred in 2002. However, doing so would have resulted in a loss of rebate payments for all Pfizer products. In the case of a health plan, the change in benefit would also likely require approval by the Department of Insurance in each state where the health plan provides benefits. In the case of a collectively bargained benefit, changes would not be possible during the contract term. Formularies and utilization controls are subject to similar administrative limitations. These real life limitations would have substantially restricted any TPP in efforts to offset the price increases that resulted from the change in AWP to WAC ratio.<sup>17</sup>

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17. October 2007 McDonough Rebuttal Report, p. 4.

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What Dr. McDonough fails to consider in her argument here is that TPPs would have an easier time offsetting price increases resulting from the alleged scheme because the artificial increases in AWP resulting from the alleged scheme were not associated with an increase in PBM or pharmacy costs.

**VII. DR. MCDONOUGH'S OPINIONS ON MANUFACTURER REBATES ARE IRRELEVANT TO THE QUESTION OF TPP MITIGATION**

12. Dr. McDonough seems to disagree with my opinion that TPPs could mitigate the effects of the scheme using manufacturer rebates by negotiating greater rebate pass-through rates with PBMs. She says that, "Dr. Willig ignores that most TPPs don't negotiate rebates, but rely on their PBMs to negotiate manufacturer rebate contracts of [sic] the TPPs' behalf. These rebate contracts are proprietary to the PBM and the terms are not known to the TPP. Rebates are earned by virtue of a product's preferred placement on the PBM's or TPP's formulary."<sup>18</sup> What Dr. McDonough fails to acknowledge here is that TPPs and PBMs negotiate the rebate pass-through percentage. However, in the McDonough Article she acknowledges exactly this point. She states that TPPs and PBMs have a variety of ways in which they share the manufacturer rebate and she points out in this article that the determination of how the rebates are split between the PBM and TPP are based on the negotiation process and that rebate dollars may be traded off for changes in administrative fees or "medication or pharmacy dispensing fees."<sup>19</sup> It is in this way, that there could be a mitigating change in the amount of rebate

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18. October 2007 McDonough Rebuttal Report, p. 4. See also, McDonough Video Tutorial, p. 11.

19. McDonough Article, at p. 24 ("Rebate allocations are based on a wide variety of criteria, ... PBMs may use rebate revenues to lower administrative fees or other



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dollars received by the TPP as a result of the alleged scheme and this is why Dr.

Hartman's aggregate damages model, which cannot capture changes in rebates, may lead to an overstatement of damages.

**VIII. DR. MCDONOUGH MISCHARACTERIZES MY OPINION REGARDING DISPENSING FEES SUGGESTING THAT MY OPINION IS THAT DISPENSING FEES ALONE WILL MITIGATE THE EFFECTS OF THE ALLEGED SCHEME**

13. Dr. McDonough states, "Dr. Willig also suggests that changes in dispensing fees paid to pharmacies could also have offset the impact of AWP increases."<sup>20</sup> Dr. McDonough then goes on to explain why changes in the dispensing fee alone could never offset the effects of the alleged scheme. "PBM contracts offer retail pharmacy dispensing fees that rarely exceed \$2.00 per prescription ... a 5% increase in a month's supply of Lipitor would exceed \$5.00 per prescription."<sup>21</sup> I never stated that changes in the dispensing fees alone could offset the affects of the alleged scheme. My opinion is, and has always been, that the dispensing fee is one of the factors over which TPPs and PBMs negotiate and that it is one of the tools that could be used by TPPs to mitigate the impact of the alleged scheme.

**IX. DR. MCDONOUGH'S OPINION REGARDING PBM CONTRACTING CONTRADICTS DR. HARTMAN'S OPINIONS REGARDING THE CONSTANT RELATIONSHIP AND THE VALIDITY OF THE IMS DATA**

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costs that are paid by the client. In some cases, PBMs use rebate revenues to buy down the cost of the medication of pharmacy dispensing fees that are charged to their clients.")

20. October 2007 McDonough Rebuttal Report, p. 5.

21. October 2007 McDonough Rebuttal Report, p. 5.

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14. Dr. McDonough points out that, “PBMs use pharmacy payment margins, or spread, as a source of income”<sup>22</sup> and that, “pharmacy network spread continues to be commonplace.”<sup>23</sup> Dr. McDonough also opined in her first report that, “[a]s the PBM industry learned of the change in AWP to WAC ratio, they were able to renegotiate pharmacy contract rates, reducing the prices paid to pharmacies to compensate wholly or partially for the increased profit margins.”<sup>24</sup> Dr. McDonough’s opinions provide support for the fact that the prices reported in the IMS data used by Dr. Hartman are not the prices paid by TPPs, but rather are the prices paid by PBMs to retail pharmacies. Her opinions also contradict Dr. Hartman’s opinions regarding the constant relationship between the discounts paid to pharmacies by PBMs and the discounts paid by TPPs to PBMs.

**X. DR. MCDONOUGH MISCHARACTERIZES MY OPINION REGARDING TPP KNOWLEDGE**

15. In the McDonough Video Tutorial, Dr. McDonough makes a statement that suggests that I believed TPPs knew that AWP price increases were the result of a conspiracy between McKesson and FDB. She says: “Dr. Willig’s theory assumes that third-party payers know that AWP price increases were effected through a scheme between First DataBank and McKesson.”<sup>25</sup> This is incorrect. My opinion is, and has always been, that TPP knowledge of the conspiracy between McKesson and FDB was not

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22. October 2007 McDonough Rebuttal Report, p. 5.

23. October 2007 McDonough Rebuttal Report, p. 6.

24. September 2007 McDonough Report, p. 13.

25. McDonough Video Tutorial, p. 7.

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necessary for TPP mitigation. TPPs observe and respond to inflation in AWP. TPPs do not need to know the source of AWP inflation to effectively mitigate price increases.

**XI. DR. MCDONOUGH MISCHARACTERIZES MY OPINION REGARDING PBM BEHAVIOR**

16. Dr. McDonough suggests, in the McDonough Video Tutorial that I, “assume that PBMs always act solely in the best interest of their third-party payer clients.”<sup>26</sup> By this, Dr. McDonough is suggesting that my opinion is that all PBMs would take action to lower reimbursements for all TPPs following the alleged scheme. This is incorrect. My opinion is, and has always been, that PBM competition, while fierce, is imperfect. PBM competition will lead to lowered reimbursements for some TPPs. It is an individual, empirical inquiry to determine which PBMs lowered reimbursements to TPPs, and which TPPs mitigated the effects of the alleged scheme.

**XII. DR. MCDONOUGH’S REFERENCE TO MY USE OF THE PERS CONTRACT AS AN EXAMPLE OF REBATE PASS-THROUGH NEGOTIATION IS IRRELEVANT**

17. In the McDonough Video Tutorial, Dr. McDonough refers to my use of the PERS / Medco renegotiations in 2001 in which PERS negotiated a higher rebate pass-through percentage with Medco saying that she was involved in this negotiation.<sup>27</sup> Dr. McDonough asserts here, and in her first report, that the increase in the rebate pass-through percentage resulting from these negotiations was unrelated to the alleged

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26. McDonough Video Tutorial, at p. 7.

27. It is unclear to me whether Dr. McDonough really was involved in this particular negotiation since her reference in the McDonough Video Tutorial is to the Public Employment Retirement System of Ohio and the contracts in my example were for the Public Employment Retirement System of California.

scheme.<sup>28</sup> This example, along with the other examples contained in the January 2007 Willig Report were designed to demonstrate, with empirical evidence, the competitive process between TPPs and PBMs that could work to mitigate the effects of the alleged scheme. As such, Dr. McDonough's possible personal involvement in that negotiation process and knowledge of the particular issues of that negotiation do not diminish the value of the example and, in fact, further demonstrate the individual and highly factual nature of TPP and PBM negotiations.

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28. McDonough Report, at p. 17.

### **APPENDIX 3**

### APPENDIX 3

#### Comments on Various Opinions Given by Dr. Hartman

#### **I. DR. HARTMAN'S ANALYSIS OF THE "BELLWETHER" DRUGS IS IRRELEVANT TO WHETHER THERE WAS MITIGATION ACROSS ALL DRUG PRODUCTS**

1. Dr. Hartman makes several arguments in the October 2007 Hartman Report that focus on the reimbursement patterns for, what he calls four "bellwether" drugs.<sup>1</sup> In fact, almost all of Dr. Hartman's analysis tables are reported results related only to these "bellwether" drugs.<sup>2</sup> Dr. Hartman's bellwether analyses include fewer than fifteen of over fourteen hundred NDCs at issue in this case. Further, these four drugs have no special relevance to or information on how TPPs responded in the aggregate to the alleged scheme. TPPs and PBMs do not negotiate reimbursements for each individual drug, but rather they negotiate broad price formulas that can be used for all drugs. Therefore, reactions from TPPs would not occur on a drug-by-drug basis, but in the aggregate. The relevant analyses in this matter then are not those that focus just on these four drugs, but rather the aggregate analyses using the GE and Cigna data, the results of which I discuss in Section III.

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1. Dr. Hartman's four "bellwether" drugs are actually five different drug dosages. He includes both Lipitor 10MG and Lipitor 20MG as one "drug." I identified four of these five drug dosages in the January 2007 Willig Declaration to make the point that the relatively large increases in AWP for these drugs in 2002 likely would have been noticed by interested parties such as PBMs, TPPs and their consultants.

2. See, October 2007 Hartman Report, at Tables 1, 2, 3, 4 (a,b,c) and 5 (a,b,c).

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**II. DR. HARTMAN'S ASSERTION THAT I HAVE ONLY  
"HYPOTHEZIZED" ABOUT THE EFFECTS OF PBM  
COMPETITION IS INCORRECT**

2. In the Hartman Video Tutorial, he asserts that, "Defense has only hypothesized that PBM competition counteracted the affects of the scheme. ... They have not tested this hypothesis."<sup>3</sup> Dr. Hartman's assertions here are wrong. In the October 2007 Willig Declaration, I conducted exactly the test to which Dr. Hartman refers and I found that there was systematic push-back by GE and CIGNA following the start of the alleged scheme.<sup>4</sup> These are results that Dr. Hartman does not refute.

**III. DR. HARTMAN ASSERTS THAT I DID NOT PERFORM  
STATISTICAL ANALYSES PRIOR TO THE OCTOBER 2007  
WILLIG DECLARATION**

3. In the Hartman Video Tutorial, Dr. Hartman states, that, "Prior to Dr. Willig's latest Declaration of October 2007, he performed no statistical analysis using micro-data measuring the amounts paid by class members for drugs at retail. We did."<sup>5</sup> I do not understand why Dr. Hartman feels that this is an important point. I performed a statistical analysis in the October 2007 Willig Declaration to respond to the first statistical analysis that Dr. Hartman provided, in the September 2007 Hartman Declaration.

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3. Hartman Video Tutorial, p. 6.

4. See, October 2007 Willig Declaration, ¶55.

5. Hartman Video Tutorial, p. 16.



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**IV. ONCE AGAIN DR. HARTMAN ERRONEOUSLY STATES THAT MY OPINION IS THAT THERE WAS ZERO IMPACT FOR ALL CLASS MEMBERS**

4. In Attachment D of the October 2007 Hartman Report, Dr. Hartman argues that I have asserted that there is zero impact for all TPP class members. As support for this, Dr. Hartman quotes my January 2007 report: "...PBMs facilitate the operation of market mechanisms that cause TPP reimbursement rates to return to or retain their levels that prevailed prior to the artificial change following the change in the AWP/WAC ratio and artificial inflation in AWP."<sup>6</sup> This statement neither says nor implies that I believe there would be zero impact for all TPPs. This statement means that TPP reimbursements, after an increase in the list price (AWP), will return to their equilibrium levels because of the market mechanism facilitated by PBMs. As long as the return to equilibrium is not immediate there can be some damage for some TPPs. Other TPPs may negotiate new contract terms that retroactively offset the effects of the alleged scheme. In those cases, the TPP suffers no impact. Said differently, this return to the competitive equilibrium will take longer for some TPPs than others and this return to the competitive price will happen through different mechanisms for different TPPs. This is why, to determine if and how much TPPs were damaged, one must evaluate damages on an individual basis. This does not mean there are no damages. It does mean that damages are an individual fact issue to be evaluated on a TPP-by-TPP basis.

5. Similarly, Dr. Hartman tries to assert that I have changed my opinion. He states:

[I]t would seem to me that Dr. Willig has changed his opinion. At ¶16 of his October 2007 Declaration, he asserts, 'It is true that if there were perfect competition

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6. January 2007 Willig Report, ¶43.

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among PBMs, then there likely would be complete mitigation for all TPPs. But, as stressed above, that is not my opinion.' As demonstrated in his opinion in January, 2007 (§52.b), that was his opinion; Dr. Willig expected complete mitigation for 'TPP reimbursement rates' without any stated exception. His opinion clearly his changed.<sup>7</sup>

Dr. Hartman is wrong. As I explained above, the quotation from my January 2007 report does not have the extreme interpretation Dr. Hartman assigns to it. As such, it is completely consistent with and, in fact, is the same opinion that I have expressed throughout all of my reports and declarations.

**V. DR. HARTMAN IS NOT USING STANDARD ECONOMIC METHODS TO CALCULATE DAMAGES**

6. Dr. Hartman states:

I agree with Dr. Willig that we must look to economic theory and empirical results to determine impact injury and damages. That is exactly what I have done. I find that the proposed Classes were impacted, injured and damaged economically as a result of the Scheme; the damages varied over time; standard economic methods and generally accepted survey data allow me to accurately calculate aggregate Class-wide damages.<sup>8</sup>

However, as I detail in Section III of this declaration, Dr. Hartman's aggregate damages model necessarily overstates damages. Standard economic theory indicates that there would be a number of complex mitigating market responses to an artificial increase in a list price such as AWP. Determining an accurate estimate of the impact of the alleged scheme net of all market responses for each TPP requires an individualized analysis. Because Dr. Hartman ignores the mitigating market responses, his characterization that his aggregate damages methodology accurately calculates aggregate damages is wrong.

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7. October 2007 Hartman Report, Attachment D, ¶8.

8. October 2007 Hartman Report, Attachment D, ¶7.

## **APPENDIX 4**

## APPENDIX 4

### Dr. Hartman's IMS Data Dilution Problem

1. Dr. Hartman's IMS data are based on more than PBM transactions at retail. Each observation also includes Medicaid transactions, cash transactions and transactions in which the pharmacy responded with AWP itself when surveyed to provide actual PBM reimbursement. Inclusion of these observations in the underlying IMS data is a further reason that Dr. Hartman's estimated damages is likely to be overstated. The problem occurs when the additional transactions are a function of AWP. When AWP increases as a result of the scheme, the mitigation through increased discounts or reduced dispensing fees is now averaged with observations that simply increase with the AWP. The result is an overstatement of TPP damages.

2. To illustrate the problem, I use a numerical example contained in Appendix Table 4.1. The example assumes that there are two types of transactions underlying the IMS data for a particular drug in a period of time. The first type of transaction is a legitimate PBM reimbursement where the payment that the pharmacy reports is  $AA = (1 - d) AWP + df$ . I assume that there are 700 units recorded in the data for this type of transaction. The second type of transaction is one in which the pharmacy reports AWP itself rather than the PBM's actual payment of AA.<sup>1</sup> In the example, I assume that there are 300 units recorded in the data for this type of transaction.

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1. This is the type of mis-reporting that IMS indicates occurs in approximately 30 percent of the pharmacies responding to its NPA survey. See Philpot Declaration, at ¶6. This is one type of dilution, but the same analysis applies when considering the inclusion of Medicaid payments and cash payments under Dr. Hartman's theory that these payments are a function of AWP.

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3. I then calculate the per unit payment in the “but-for” scenario where the AWP/WAC ratio stays at 1.2 and the discount off AWP stays at 15 percent. The per unit payment for the first type of transactions (based on AA) would have been \$85.00. Given the increase in the AWP/WAC ratio to 1.25 and an increase in the discount to 17 percent in the “actual” scenario, the per unit payment for the first type of transactions is \$86.46. Therefore, per unit damages for the first type of transaction are  $\$1.46 = \$86.46 - \$85.00$ .

4. The problem is that in the IMS data, the two types of transaction are commingled. Therefore observed data includes the transactions where the pharmacy reports AWP rather than AA. For those types of transactions in the “but-for” scenario the per unit payment is \$100.00, while the observed actual payment is \$104.17, resulting in damages of \$4.17 because the payment increases by precisely the increase in AWP itself. Therefore, the observed damages in the mixed data that includes both types of transaction is the weighted average of \$1.46 and \$4.17, or \$2.27.

5. The example shows that Dr. Hartman’s methodology would generate damages of \$2.27 per unit, when the measure of damages he would have had if there had not been dilution with data transactions other than legitimate PBM transactions would have been \$1.46 per unit, resulting in a 36 percent overstatement of damages. This is a numerical example that illustrates the bias in the analysis. I do not claim that the magnitude of the bias is 36 percent. Determining the true magnitude of the bias would require analyzing IMS data that is not diluted with Medicaid, cash and mis-reported observations.

6. In summary, by using data that are based in part on observations that are not legitimate PBM observations in the IMS data, the apparent damages calculated by Dr. Hartman overstate true damages.



## **APPENDIX 5**



## APPENDIX 5

### **Dr. Hartman's Analysis of IMS Data Indicates Statistically Significant Overall Market Response**

1. In the October 2007 Hartman Report, Dr. Hartman argues against using the aggregated evidence because he claims it imposes an assumption that all drugs follow the same time trend and "according to standard statistical practice, if my data allow me to test for the imposition of this assumption of commonality, I must do so."<sup>1</sup> My analysis imposes no such assumption of commonality. Estimating a single, average time trend across drugs does not impose the assumption that each individual drug must follow that average trend any more than computing an average from any sample imposes the assumption that all observations in the sample are the same. That is, given that each drug in Dr. Hartman's sample is in the data for the full period, the time trend estimated from a single, stacked regression is precisely the average of the estimated time trends for each separate drug.<sup>2</sup> Dr. Hartman claims that using this average as a summary statistic somehow imposes the assumption that all the trends are the same. There is no such assumption implied by the use of an average. Computing an average, and then testing statistically whether that average is negative, is an entirely standard way of summarizing

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1. October 2007 Hartman Report, at Attachment D, ¶31.

2. See A. Goldberger, *A Course in Econometrics*, 1991, pp. 331-332 for the result that in a stacked regression in which the X variables are the same for each observation (in the current context, meaning all drugs are observed for the full time period), the stacked regression estimate is simply the average of the separate estimate for each drug.

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the full body of evidence from the sample on the existence of push back on the whole, across all drugs.<sup>3</sup>

2. Dr. Hartman further argues that "we should seek to find that time pattern of reimbursement changes revealed by the data for each drug, rather than impose an artificially common time pattern that has been rejected by the data."<sup>4</sup> Again, I am making no such imposition. I am simply using the stacked regression as a way to compute the average trend, which is the relevant measure here because whether there was variation in push back across drugs is not at issue in this case. Rather, having used the average trend across drugs to demonstrate that there was, indeed, push back, the relevant issue becomes the degree of variation in this push back across TPPs. It is determining this dimension of variation that Dr. Hartman's methodology does not accomplish and that necessitates the use of individuated analysis for each TPP.

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3. See A. Goldberger, A Course in Econometrics, 1991, pp. 8-9 for a discussion of using means as summary statistics. "A large part of empirical econometrics is estimating population conditional mean functions from a sample. That is, economists very often want to learn how the average value of one variable varies in a population with one, or several, other variables...in introductory statistics courses, we have learned all about estimating population means. In particular, we have learned that the sample mean is an attractive estimator of a population mean..." See also, W. Greene, Econometric Analysis, 4<sup>th</sup> Edition, p. 97.

4. October 2007 Hartman Report, at Attachment D, ¶35.

## **APPENDIX 6**

## APPENDIX 6

### **Dr. Hartman's Model May Overstate Damages By Failing to Account for WAC Changes Resulting from the AWP/WAC Ratio Increase**

1. Dr. Hartman's damages model does not account for the possibility that any manufacturer could have modified the increase in the WAC for its drugs as a way to avoid losing sales when the AWP/WAC ratio increased. Dr. Hartman's model uses the WAC from the period three month prior to implementation of the increased AWP/WAC ratio as a proxy for the "but-for" WAC. The problem is that the WAC three months prior to the ratio change (Hartman's "but-for" WAC) is likely to be lower than the observed WAC during the damage period and lower than the correct "but-for" WAC because of inflation in WAC. This is because manufacturers may have slowed the growth of WAC in order to keep AWP at its "optimal" level in the view of the manufacturer. Therefore, the correct "but-for" level of WAC for any drug was likely higher than the observed actual WAC during the period after the increase in the AWP/WAC ratio.

2. Dr. Hartman's error leads to an overstatement of damages. I illustrate the point with a numerical example in Appendix Table 6.1. In this numerical example, I assume that there is no adjustment to the alleged scheme through changes in discount or dispensing fee. Instead, the manufacturer moderates growth in WAC in order to offset the increased AWP/WAC ratio. In this example, Dr. Hartman would find substantial damages even though there are none.

3. Assume that observed WAC three months prior to the ratio change in \$84.50. Assume that the discount is 15 percent and the dispensing fee is \$1. Then AWP three months prior would be \$101.40 and AA would be \$87.19. Then after the

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AWP/WAC ratio changes, WAC rises to \$85.00, AWP rises to \$106.25 and AA is \$91.31. Dr. Hartman would find damages of \$4.12 in this circumstance.

4. Now assume that the manufacturer is not happy about the increase in the AWP/WAC ratio because it would lead to a reduction in sales as TPPs and their members reduce the quantity demanded for the drug due to higher costs. One recourse for the manufacturer is to moderate the growth in WAC. In this circumstance, the manufacturer would have increased WAC from \$84.50 to \$88.54 “but-for” the increase in the AWP/WAC ratio, but instead increased WAC from \$84.50 to \$85.00. In this circumstance the “but-for” AWP would have been \$106.25 absent the increased AWP/WAC ratio, which exactly matches the observed AWP of \$106.25 with the increased AWP/WAC ratio. Even without any mitigating changes in discount or dispensing fee, the payment (AA) remains at \$91.31 and therefore there are no true damages.

5. In this example, despite no actual harm to the TPP, Dr. Hartman’s model would generate damages of \$4.12 per unit. This example illustrates that Dr. Hartman’s model necessarily overstates damages if manufacturers modified the growth in WAC for any drug in response to the increased AWP/WAC ratio. Dr. Hartman’s claim that he accounts for growth in actual WAC over time does not address or solve this problem.

## Appendix Table 6.1

## WAC Change Example

Methodology	"But-For" (AWP/WAC Ratio = 1.2)					Actual (AWP/WAC Ratio = 1.25)					Per Unit Damage
	WAC	AWP	Discount	Dispensing Fee	Payment (AA)	WAC	AWP	Discount	Dispensing Fee	Payment (AA)	
Hartman's Use of WAC 3 months prior to AWP/WAC ratio change	\$84.50	\$101.40	15%	\$1.00	\$87.19	\$85.00	\$106.25	15%	\$1.00	\$91.31	\$4.12
True "But-For" WAC assuming manufacturer adjusted WAC to offset impact	\$88.54	\$106.25	15%	\$1.00	\$91.31	\$85.00	\$106.25	15%	\$1.00	\$91.31	\$0.00